THE ROLE OF RISK ASSESSMENT IN MANAGING RISK

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Introduction

The new landscape of the 21st century, while promising unparalleled advancements and growth, is fraught with a variety of *hazards and risks.* As multinational companies operate across borderless and timeless dimensions of the international market place, coupled with rapid transportation systems, the risks of introduction and spread of emerging and re-emerging diseases and other risks continue to expand across the globe (Krause, (Ed.) 1998, Fauci, 1998). Recent examples of emerging/re-emerging diseases and pests of livestock and crops include Hong Kong Avian Influenza (H5N1), *E. Coli* (O157), foot and mouth disease (FMD), bovine spongiform encephalopathy (BSE), classical swine fever (CSF), Nipah virus, West Nile Virus (WNV), New Castle Disease, sorghum ergot, karnal bunt and pfisteria,(Taylor et. al., 2001) to name a few. Once introduced into a country or region, the concentration of large agricultural enterprises and intensive production systems and global distribution of foods further hastens the spread of diseases and pests. The US food and agricultural system constitutes the largest positive element in the US international trade balance and involves assets in excess of a trillion dollars. Since it provides almost 20% of the nation's employment, such threats are of great concern. Most significantly too, recent threats from bioterrorism have added a more urgent dimension to either prevent and/or minimizing the catastrophic consequences that may arise as a result of introduction of such dangerous diseases and pests.

The wide array of new and re-emerging pests and diseases impacts not only agricultural productivity, but also global competitiveness, food security, food safety, bioterrorism and by extension, the health of people. The challenges of emerging agents from a wide array of global sources and causal factors must be addressed on several fronts.

In order to counter such on-going threats and challenges, advancing and refining research in risk analysis methodologies, coupled with reliable and effective surveillance systems for data collection about diseases and pests and preparing technologically and quantitatively trained scientists becomes a priority agenda. Risk analysis (composed of the triplets of risk assessment, risk management and risk communication) and mathematical models based on the underlying epidemiology and transmission mechanisms of diseases and pests can help the agricultural scientific community to understand and anticipate the spread of these risky agents and to evaluate the potential effectiveness of different mitigations in managing the risks posed by these threats.

Global agriculture and international trade: Current global markets demand control of plant and animal pests and diseases and assurances of safe foods for their respective societies. But the biggest potential barriers to trade in the free trade markets that exist today are plant and animal health restrictions. The importation of animals, plants and their byproducts always involves a degree of disease risk, pest infestation risk or consumer health risk for the importing country. For example, Americans get about 28% of their agricultural produce from around the world. But such bounty of agricultural products comes at the cost of more foodborne illnesses such as *E. coli* (Torok.,et.al. 1997) and others. The problem is further compounded by the decline and/or deteriorating surveillance programs and diagnostic laboratories and appropriate technologies needed to identify new pests and diseases rapidly and reliably. Regardless of what the reasons may be, the exclusion of an animal or plant product or byproduct due solely to the presence of disease/pest in an exporting country is no longer a defensible policy. This new era of free trade agreements, regionalization, and scientifically based policy making, demands a thorough quantitative assessment of all factors involved in making policies and regulations to facilitate international agricultural trade.

More specifically, international agreements such as the World Trade Organization (WTO) and North American Free Trade Association (NAFTA) require sanitary/phytosanitary (SPS) regulations that are supported by science-based risk assessments so as to manage potential risks while promoting global trade. Article 5 of the SPS agreement states: “Members shall ensure that their SPS measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.”

Since import/export of agricultural products are under the purview of United States Department of Agriculture/Animal and Plant Health Inspection Service (USDA/APHIS), the agency is constantly challenged to consistently and transparently assesses, manage, and communicate risk factors to justify regulatory and programmatic decisions. The agency’s mission statement states: “To meet the expanding and evolving expectations of its various stakeholders, the agency must continue to strengthen its risk analysis capabilities”. Obviously, risk analysis serves as a powerful problem solving and decision-making tool in import/export of agricultural products. But what is more critical is that risk analysis relies upon and is linked conceptually and scientifically to the discipline of epidemiology. One can extend the same logic to the role for economics in risk analysis. However, this paper is focused upon the rational and science-based link between epidemiology and risk analysis. Without a thorough grounding in the biology of risk agents (i.e. the epidemiology of diseases and pests of animals, humans and/or plants) and a detailed description and decomposition based on the logical link between Epidemiology & Risk Analysis, the management and communication of risk may lack scientific validity.

The Epidemiologic Framework to Risk Analysis

Let us first consider definitions of epidemiology and risk analysis as pertains to this paper. We define epidemiology as the study of the dynamics of health/ill health processes in populations. It is often directed at problem solving and decision or policy making at the population level. On the other hand, risk analysis is defined as the practice of decision making based on scientific evidence (Risk Newsletter, 2000). Like epidemiology, risk analysis is often focused on population-based studies although both methodologies can be applied to any population such as cellular, molecular, genomes and others. This is because in epidemiology, the population under study can be groups of animals (e.g. herd health), humans (e.g. public health), plants (phyto-epidemiology), cellular and molecular populations (molecular epidemiology), or populations of genes (genetic epidemiology). Epidemiology is a discipline that can be applied to the study of population dynamics from the molecular (micro-epidemiology) to higher levels (macro-epidemiology) of population dynamics. This breadth of epidemiology provides risk analysis with the framework for its application in a vast array of population-based studies from genomics and biotechnology to international trade.

The link between epidemiology and risk analysis is rational and intuitive. The two areas complement and supplement each other. In epidemiology, the basis for reasoning and explanation, the opportunity for dealing with choices, risks or benefits especially in the face of uncertainties, and the need to analyze and manage imperfect data are common occurrences. The same applies to risk analysis. The dilemma is that the paucity, incompleteness and uncertainty of available data further complicate quantitative models. Yet, both epidemiologic problem solving and decision-making as well as risk analysis often must proceed in the face of uncertainties and limited knowledge. A risk assessment is never complete nor is it static. As more knowledge and information is gained over time, a risk assessment can be revised and updated as appropriate.

To handle the types of challenges described above, computer modelling (Risk Analysis and Epidemiologic Modelling) provides a powerful alternative tool to traditional empirical (field or laboratory) studies. Computer models provide a mechanism for approximating biological interactions, via biomathematical expressions that can be tested using a computer model as the experimental medium. This new approach is the realm of *computational science* (Pool, 1992.). Computational science integrates the two traditional areas of empirical and theoretical sciences. It also builds upon and extends the methods and tools available to research by exploiting computational resources. Computer models now provide alternative avenues where systems, which may be complex, too large, not feasible because the information is scanty and uncertain; or the cost is too prohibitive, can be approximated and simulated realistically. With this premise, at Tuskegee University (TU), we have been carving a niche in a subset of this new science that we refer to as "*computational epidemiology*" (Habtemariam et. al. 1983 - 2004). For further information, we invite the reader to peruse our website at: *http://compepid.tuskegee.edu/compepid/index.html*.

Integrating Epidemiologic Modelling and Risk Analysis

A detailed analytic understanding of the epidemiology of a population under study and a decomposition of all relevant determinants of health and disease are prerequisites for quantitative and qualitative risk assessments. The method of decomposition of any epidemiologic or risk assessment task relies on what we call the Epidemiologic Problem Oriented Approach (EPOA). As in any problem solving and decision making exercise, the EPOA essentially consists of a problem identification/definition/characterization component (step #1), followed by a problem management component (step #2). We use the classical epidemiologic triad (epidemiologic triplet) consisting of host, agent and environment interactions, and examination of agent transmission pathways and spread of disease both in time and space as the first key step to risk assessment (Problem solving step #1). When conducting risk assessments, rational intervention strategies (mitigations) that minimize the risk of transmission and introduction of a disease or pest are then integrated into such an epidemiologic framework. The second set of triad, composed of prevention/control, treatment or therapeutics to eliminate a risk agent and health maintenance/promotion is the decision making step. The two triads are interlinked by diagnostic procedures used in identifying and characterizing the risk agent when possible. We use the EPOA as the prerequisite for all risk assessments that we conduct at Tuskegee University. (Figure 1)

Once the epidemiology is decomposed using the EPOA methodology and the relevant scientific references and evidence is gathered, the risk assessment process follows. Although the generic term risk analysis is composed of: a) risk assessment, b) risk management, and, c) risk communication, our emphasis in this paper is on risk assessment. These components are part of the classical problem solving steps of: a) problem identification and characterization (risk assessment), and, b) problem management (risk management and risk communication).(Figure 2) It is noteworthy to emphasize that both risk management and risk communication rely on sound risk assessments, which may be qualitative or quantitative in nature.

Approaches to Managing Risk Through Risk Assessment

Risk mitigation in this paper is broadly defined to include all activities and resources required to: a) prevent introduction of risk agents, b) eliminate or stamp out the risk agent if possible, and/or c) manage the risk event by taking steps to minimize or reduce the risk once introduced into a region. We contend that effective approaches to risk management rely upon: a) sound science-based risk assessment which in turn depends on a detailed understanding and decomposition of the epidemiologic factors and the transmission pathways for the risk agent under study, and, b) education and information sharing (nationally and internationally).

The USDA/APHIS has established six strategic mission priorities to strengthen key components of its animal and plant health protection system. These are: 1) strengthening emergency preparedness and response, 2) ensuring the safe research, release and movement of agricultural biotechnology, 3) managing issues related to the health of US animal and plant resources and conflicts with wildlife, 4) resolving trade barrier issues related to sanitary and phytosanitary (SPS) issues, 5) reducing domestic threats through offshore threat assessment and risk-reduction activities (e.g. reduce the threat of emerging/re-emerging animal and plant diseases and pests through training and technology transfer to strengthen the infrastructure and capacity of developing countries, and, 6) conducting risk assessments and expanding methodologies for risk assessments to reduce the risk of invasive species introductions. Three of these six key objectives involve risk assessment and SPS issues either directly or indirectly.

Three case studies, which involve partnerships between TU and USDA/APHIS and the role that this partnership plays in advancing the mission of the agency, are presented below.

1. **Performing epidemiologic risk assessments that could allow the quantitative assessment of mitigations to manage risk**.

Although risk assessment is still in its infancy in the animal and plant health area, some have been documented in the literature (Berensten, et al. 1992; Chioino, et al., 1998, Gardner and Lack, 1995; Krystynack and Chalebois, 1987; McElvaine et al. 1993; Miller, et al. 1993; Morley , 1993; Yu et al., 1997). To illustrate how this strategy works, several case studies conducted at Tuskegee University could serve as examples. At the *Center for Computational Epidemiology, Bioinformatics and Risk Analysis (CCEBRA),* at Tuskegee University, we have collaborated with USDA on over a dozen risk assessment projects. With funding from USDA/APHIS, we have conducted quantitative risk assessments for the likelihood of introduction of foot and mouth disease virus (FMDV) through importation of frozen beef, mutton or processed cheese (CCEBRA Report 1-5).

The introduction of citrus canker and citrus black spot and introduction of hog cholera through pork imports have also been examined. In collaboration with the Harvard Center for Risk Analysis and several USDA agencies, we have developed a dynamic risk assessment for the possible introduction of BSE into the USA (Cohen et al. 2001; Habtemariam T. et al. 2002, Cohen et al. 2004). With funding support from USDA/CSREES, we have developed an on-line risk analysis course and a Hazard Analysis and Critical Control Points (HACCP) course and we have used these resources for training scientists and others. We have expanded collaborations among institutions such as: Harvard Center for Risk Analysis; University of Maryland, Center for Technology Risk Studies; University of West Indies, Trinidad &

Tobago; Addis Ababa University, Ethiopia; Alemaya University, Ethiopia; University of Alabama, Tuscaloosa; University of Alabama, Birmingham; University of Nairobi, Kenya; Makerere University, Uganda; Sokoine University, Tanzania, and others.

The risk assessments developed at TU all rely on using the EPOA framework. Using the EPOA methodology, the components of the two triads are decomposed and scientific evidence on each is gathered; then risk pathways are developed, additional scientific data are gathered, parameters estimated, a risk assessment computer model developed and Monte Carlo simulations are run to evaluate, address and answer specific risk agent introduction questions.

The case study involving the assessment for the likelihood of introduction of FMD virus through cheese importation is provided as a specific example of how an epidemiologic risk assessment model can serve to evaluate approaches to managing risks of introduction of unwanted agents.

The case for assessing the risk of introduction of FMD virus via cheese importation: A quantitative risk assessment (QRA) was conducted to determine the likelihood of introduction of foot and mouth disease (FMD) virus into the USA via imported cheese. The study addresses only the risk of introduction of FMD virus via imported cheese but does not consider the consequences of FMD virus introduction and the subsequent economic, environmental and epidemiologic impacts. The imported cheese may include several varieties of hard, semi hard or soft cheeses. The cheese may be imported from FMD endemic or FMD free countries and the source milk may either be pasteurized or unpasteurized.

The steps in the QRA consisted of developing an epidemiologically sound conceptual model that displays the risk pathways culminating in the introduction of FMD virus via imported cheese. Scientific evidence was gathered and documented from various sources (Blackwell, et. al. 1982, Donaldson, 1997, Hyde, et. al. 1975, Code of Federal Regulations 2002, Leeuw, 1980)**.** Parameters were estimated using data collected from published literature, expert opinions, industry consultations, and governmental and international databases. Risk management options were incorporated and various risk assessments scenarios were examined. Using a probabilistic risk pathway scenario tree **(**Figure 3**)**, the most critical points in cheese production where FMD virus may be introduced or survive were examined systematically. Four risk pathway nodes along with three key mitigations (pasteurization, maturation to pH 6.0 or less and ageing of cheese over several days/months) that are critical in reducing the risk of FMD virus introduction form the core of this risk assessment.

Computational models that relied on probability distributions specific to the FMD risk agent were developed. Using the model, Monte Carlo simulations were performed to estimate the likelihood of introduction of FMD virus via imported cheese. The analysis was performed using @Risk software (Palisade Corporation) on a Gateway Pentium IV computer. We emphasized simulations that generate families of distributions rather than point estimates. At each node of the scenario tree the FMD viral infectivity was tracked until the total FMD viral infectivity was determined at the final node. To develop the corresponding distributions for FMD infectivity a total of 10,000 iterations with six simulations were performed. The amount of the imported cheese (in kg) that an animal should consume by oral route to get infected was also computed. These values are calculated by dividing the amount of FMD virus infective doses capable of initiating an infection in cattle and/or pig by oral route (that is $10^{6.0}$ ID_{50} and $10^{5.0}$ ID_{50} respectively; Donaldson, 1997) by the total number of infective doses per kg of imported cheese per year. Various scenarios were simulated and rigorous sensitivity analyses were performed to assess model stability and the impact of parameter changes. Selected summary results are presented in Table 1 **and** Figure 4**.**

Based on the table and graph shown, a risk manager can evaluate the various options to decide what the best alternative will be to balance the risk of introduction verses. the potential negative consequence in loss of taste and quality of cheese. If the cheese is aged for a long period of time it becomes rancid and thereby loses its marketability. This example shows how quantitative risk assessment can be used to facilitate managing risk by providing various options or scenarios that a decision maker can review in order to make effective decisions. Because it is based on sound epidemiologic (scientific) decomposition and valid evidence, it can be effectively communicated to all stakeholders.

2. International training and information sharing as a tool in risk management: This approach is geared at risk prevention/mitigation so to minimize or eliminate risk agents at the source; build international collaborations; and strengthen the infrastructure and expertise in risk assessments.

Once again, an international project just completed at TU is presented below as a case study to show how this activity supports one of the key objectives of USDA/APHIS. This international project is also consistent with article 9.1 of the SPS agreement, which states: “Members agree to facilitate the provision of technical assistance to other Members, especially developing country Members, either bilaterally or through the appropriate international organizations. Such assistance may be, *inter alia*, in the areas of processing technologies, research and infrastructure, including in the establishment of national regulatory bodies, and may take the form of advice, credits, donations and grants, including for the purpose of seeking technical expertise, training and equipment to allow such countries to adjust to, and comply with, sanitary or phytosanitary measures necessary to achieve the appropriate level of sanitary or phytosanitary protection in their export markets”.

Although the World Trade Organization’s (WTO) Agreement on SPS established standards for agricultural trade, many developing countries lack resources and technical expertise to comply with the SPS Agreement. Nowhere is this lack more acute than in Sub-Saharan Africa. To address this problem, at least in part, Tuskegee University (TU) in partnership with United States Department of Agriculture’s Animal and Plant Health Inspection Service (USDA/APHIS) was awarded a United States Agency for International Development (USAID) Africa Trade and Investment Program (ATRIP) grant to provide Risk Analysis Training and SPS Capacity Building activities in Sub-Saharan Africa. The goal was to strengthen Sub-Saharan Africa’s ability to comply with the requirements of the SPS Agreement through Risk Assessment Training.

The key strategy was to first create shareable resources in epidemiologic modeling and risk analysis combined with an appropriate application of statistics with emphasis on probability distributions. With this in mind, TU and USDA/APHIS developed internet and CDROM-based online courses as well as hardcopy texts in epidemiology, biostatistics and risk analysis, committed its most experienced scientists to this partnership and embarked on presenting workshops and related activities during the 2002 – 2004 period. The partners provided six workshops in risk analysis and SPS capacity building and trained 67 African scientists from 15 African countries (Table 2). The workshops emphasized generic methods that rely upon epidemiologic frameworks that integrate risk assessment, risk management and risk communication**.** A variety of case studies that showed how epidemiology provides the framework for risk analysis models for human, animal and plant diseases and pests using EPOA methodology were presented. Stochastic and deterministic models undergirded by sound epidemiologic concepts of population dynamics and systematic examinations of transmission pathways of risk agents were considered. Both qualitative and quantitative risk assessment approaches were presented.

As result of these workshops, at least five African universities introduced risk analysis in their curriculum. This change in the curriculum is expected to hasten the development of in-house expertise in risk analysis and in SPS compliance. The need for developing surveillance systems for pests and diseases in Africa and strengthening diagnostic laboratories is also well recognized. However, because of lack of resources (primarily funding) it will be quite sometime before they will be able to establish or strengthen their infrastructure in these important and critical areas. Quite impressively, in 2004, the First Pan-African Conference on SPS Capacity Building & Risk Analysis was held in Addis Ababa, Ethiopia. At this first Pan-African Conference, 40 papers on various topics of Risk Analysis were presented. The Project can be perused at: http://compepid.tuskegee.edu/ATRIP/index.htm. This project demonstrated convincingly that a lot can be accomplished within a reasonable time once a genuine effort is invested to help the developing countries in SPS and risk assessment capabilities.

The Benefits of International Training

Through this project, human capacity for SPS compliance and science-based risk assessments was strengthened. Opportunities for global trade involving developing countries were increased and relationships between African and the USA were improved. Such an increased collaboration and genuine goodwill between African countries and the USA on SPS issues and WTO related matters, in the long run, would increase opportunities to reduce the risk of foreign pests and disease (at the origin). Products will be traded only under science-based and transparent risk assessments. Resources that include Internet and CDROM based risk assessment resources for information sharing, mentoring and on-going support have been created and are already being used both within the USA and internationally. For example, based on these shareable resources, Collaboration with PAHO/WHO was initiated, thus expanding the training activities through three workshops that were given in the Caribbean region.

In addition to the workshops, the project provided each participant with several CDROMs and hard-copy syllabus for Tuskegee's on-line risk analysis course, a risk assessment textbook, and a workbook with examples of plant and animal risk assessments, training exercises and literature references. We also provided each country with at least eight computers equipped with the appropriate software, to enable them to conduct quantitative risk assessments as well as to begin to collect and store and manage their respective surveillance databases. All countries are expected to benefit from global trade and the capacity building efforts described in this project. In addition to increasing Africa's ability to participate in trade, the benefits of the project include enhanced food security and stability for African countries, reduced sanitary and phytosanitary risks to Africa's trading partners, including the United States. This will also facilitate maintenance of stronger linkages between the United States and African countries on SPS issues of mutual concern.

TU scientists have developed strong multinational and regional partnerships with African governments and universities. Sub-Saharan partnerships include five universities (Addis Ababa University, Faculty of Veterinary Medicine and Alemaya Agricultural University, Ethiopia; University of Nairobi, Faculty of Veterinary Medicine, Kenya; Makerere University, Uganda, Sokoine University of Agriculture, Tanzania), three regional organizations; Southern Africa Development Cooperation(SADC), and Council for Scientific and Industrial Research(CSIR) Ghana, representing West African Economic and Monetary Union, (WAEMU); and Common Market for Eastern and Southern Africa (COMESA). We can build on these partnerships to advance SPS and WTO related activities of mutual benefit to the USA and Africa, thereby furthering the mission of coalition building, which can be of strategic benefit in global negotiations.

This type of approach to risk prevention/mitigation, i.e. international training and information sharing, in the long run will lead to the reduction and even possible elimination of risk agents at the source;

promote coalition building international collaborations; strengthening the infrastructure and expertise in risk assessments.

3. Expanding Risk Assessment Methodologies: Continuous learning and expanding the risk assessment methodologies could serve as a strategic avenue to strengthen and advance risk assessment for managing risk. It will also promote the harmonization and transparent application of SPS regulations. Recognizing that ongoing learning and introspection and review as being critical to the strategic mission to an organization, and especially in such fast changing times, the USDA and Tuskegee University are partnering in organizing an International Conference for Risk Assessment Methodologies. The International Conference is designed to invite world renowned experts to review currently used risk assessment methodologies, evaluate strengths and weaknesses and provide recommendations as to how best to proceed forward. The second portion of the session will involve examination of newer and innovative tools that may be beneficial to advance and expand the risk assessment toolbox. Invited scientists spanning both the developed countries as well as developing countries are expected to attend. Additionally, scientific evidence and legal issues as how these impact risk assessments and the best methods to balance both of these sides will be explored. The Conference is scheduled to take place in Washington DC. August 9 – 11, 2005. A draft website with the draft agenda is available for perusal at:
http://compepid.tuskegee.edu/riskassessment/frontpage.htm

Strategic Needs for the Future

Building a Global Surveillance System: Enhancing diagnostic laboratories and surveillance systems: Identifying health threats from outside the US borders and reducing those threats at the source requires reliable and effective epidemiologic intelligence that relies on sound surveillance systems. Additionally too, SPS risk assessment and ultimately, trade relies on two critical and inter-related components. First, countries must have a reliable infrastructure for animal and plant disease and pest surveillance and for food safety surveillance. Second, they must have access to timely and at least reasonably reliable national or regional diagnostic laboratories. Pest and disease diagnostic capability is critical for access to world markets.

For example, a threat assessment/emergency response system that will provide a scientific interface between existing knowledge of plant and animal diseases and pests and food safety and their effective control at the farm level via sound risk analysis and epidemiologic modeling will become a vital strategic resource. Through a global georeferenced database system that can be accessed by global partners, it will be possible to collect surveillance information to enhance the ability to find information relevant to an emerging problem by collecting data in many places (nationally and internationally). The information can then be shared locally, regionally, nationally and internationally. Such a resource will promote communication and interaction among scientists and others in virtual links. The challenge is to develop intervention strategies at several key points based on available surveillance intelligence information. These include surveillance and monitoring of “imports”, “phytozoonoses”, “zoonoses” and “food-borne diseases” with the purpose of preventing health risks from reaching humans and/or negatively impacting agricultural trade (Figure 5).

Coupling of intelligence information to expertise (knowledgebase) and resources to identify and/or manage an emerging risk.

If a globally accessible digital resource center with databases of African and other developing country scientists and experts is developed, and if a surveillance database of animal and plant diseases and pests and food safety is available. Then, when an emerging threat is suspected or is recognized, a team of global experts could be assembled to respond to it expeditiously. In the short-term, the response could deal with early problem identification followed by effective intervention strategies. In the long-term ongoing collaboration in research, education, surveillance and related tasks will be key to maintain a ”heads-up’ approach to minimize emerging risks in the future. Reports, risk assessments and related knowledge-based experiences of experts can be shared easily and conveniently by accessing information about emerging diseases and pests of plants and animals and food safety. The same global digital resource center can foster effective communication among scientists, and decision makers. Satellite based data gathering and Geographic Information Systems (GIS) remote sensing satellite imagery data and Global Positioning Systems (GPS) and related technologies may be refined to serve as predictive tools to show the potential spatial and temporal distribution of risk factors and potential spread of emerging infections or pests. Although major obstacles including issues such of national security and terrorism, privacy and confidentiality concerns and lack of resources are to sorted out, the prospect of global cooperation and epidemiologic intelligence gathering is already in progress even if in a limited way. Global cooperation can be enhanced and strengthened significantly if funding and technology transfer and related infrastructure building is promoted actively and effectively by the developed countries of the world. This strategy could be the most effective way to counter world-wide bio-terrorism, promote global trade, expand democratic governance and reduce poverty and disease world-wide.

Summary

The role of risk assessment in managing risk during this new century has to be viewed from a broader perspective and with a long-term view in mind. There are several challenges that organizations face especially those in problem solving sand decision making arena. The challenges include:

a) Emerging and re-emerging diseases and pests arising constantly and expected to increase in the future,
b) Global interconnectedness driven by trade and fast transportation technologies which increases the risk and spread of risk agents unintentionally,
c) Demographic changes and ethnic and cultural diversity which brings changes in food habits and preferences that also leads to unintentional introduction of risk agents through imported foods and related products,
d) Bioterrorsim and the intentional introduction of risk agents

Although these challenges are immense, strategies that combine short term with long-term benefits need to be developed. Some of these strategic opportunities that could bear fruit and become effective in managing the vast array of risk agents and problems are:

- Surveillance Systems for global epidemiologic intelligence gathering
- Use of global digital resources for reporting and information sharing
- Fast response teams and strategies (supported by reliable diagnostic laboratories with rapid, cost effective but reliable test systems).
- Continuous learning and innovation to expand and/or optimize strategic tools for problem solving and decision making
- More than anything else, long term commitment to international training and technology transfer coupled with ethical trade that is geared towards economic equity instead of the rich getting richer and the poorer countries getting worse off could be the key strategy that could bring long lasting benefits for all stakeholders.

Finally, it will be advantageous to maintain and strengthen the momentum generated already as described herein by continuing to support the partnerships and collaborations for international training and technology transfer. These partnerships could be leveraged to advance risk assessment and SPS activities and to advance USA interests globally.

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Figure 1. The Epidemiologic Problem Oriented Approach (EPOA)

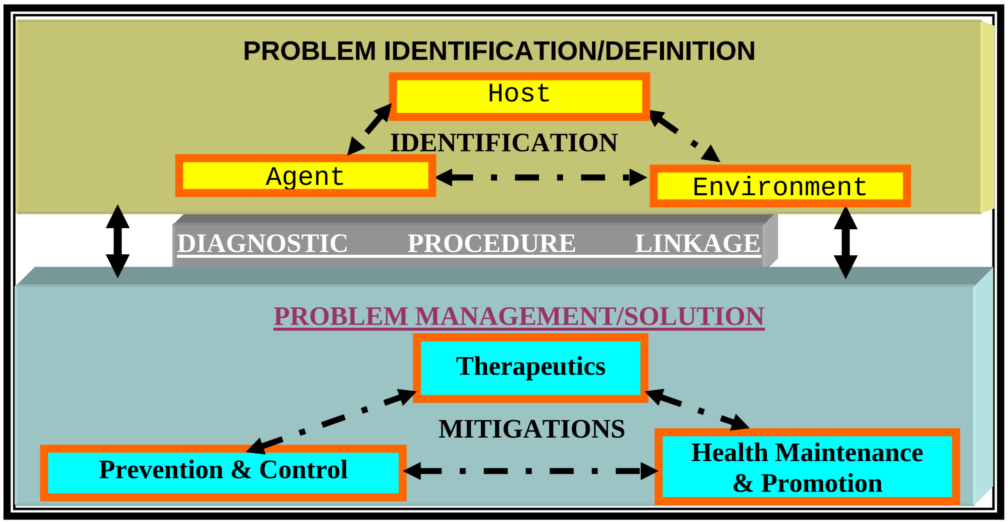


Figure 2. Risk Analysis Triplets/EPOA

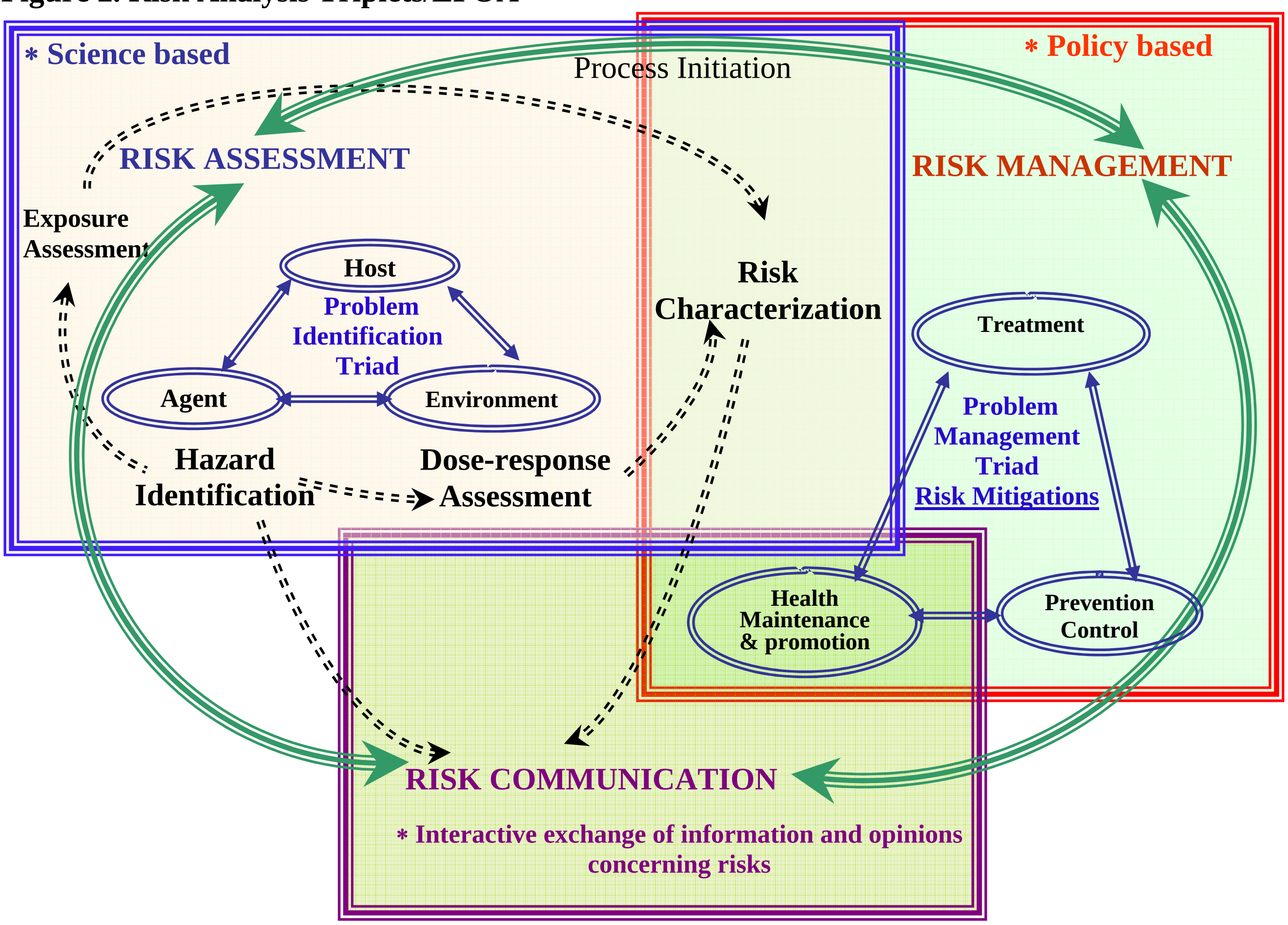


Figure 3. Scenario Tree for FMD virus introduction into the USA through importation of cheese.

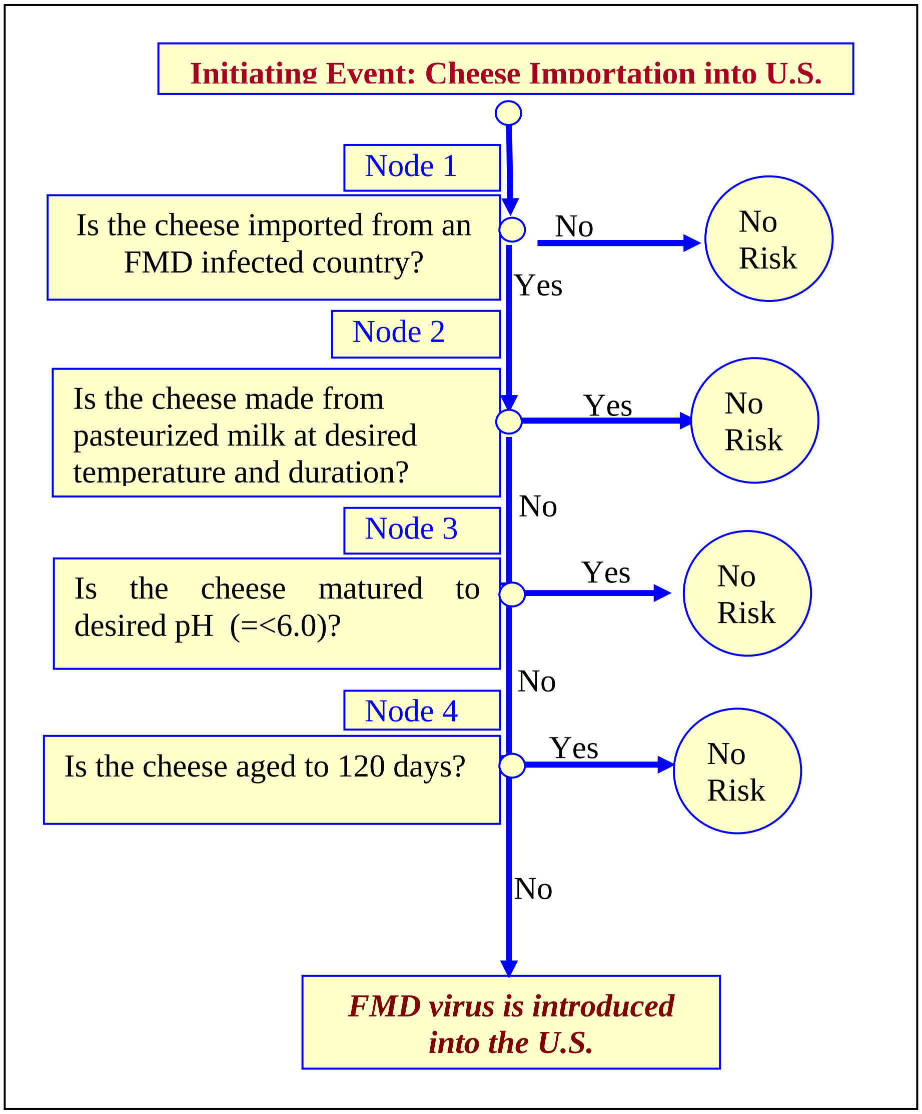


Table 1. Expected values of infectivity of FMDV (number of ID_{50}'s) at various ageing days

Ageing in days		0 day	15 days	30 days	60 days	75 days	90 days	120 days
Total FMDV infectivity (number of ID_{50}'s) in all cheese made from	pasteurized milk	1.2×10^{9}	3.63×10^{2}	8.12×10^{0}	0	0	0	0
	unpasteurized milk	2.4×10^{10}	2.13×10^{5}	1.41×10^{4}	9.25×10^{2}	3.86×10^{2}	1.89×10^{2}	6.1×10^{1}
	From both types of milk	2.6×10^{10}	2.14×10^{5}	1.41×10^{4}	9.25×10^{2}	3.86×10^{2}	1.89×10^{2}	6.1×10^{1}
FMDV infectivity number of ID_{50}'s per kg of imported cheese made from	pasteurized milk	1.58×10^{1}	5.2×10^{-6}	1.2×10^{-7}	0	0	0	0
	unpasteurized milk	4.91×10^{7}	4.36×10^{2}	2.87×10^{1}	1.89×10^{0}	7.9×10^{-1}	3.9×10^{-1}	1.2×10^{-1}

Figure 4. Cumulative distribution of FMD total virus infectivity in terms of ID_{50} in all imported cheese: scenarios where cheese is aged for 15, 30, and 60 days.

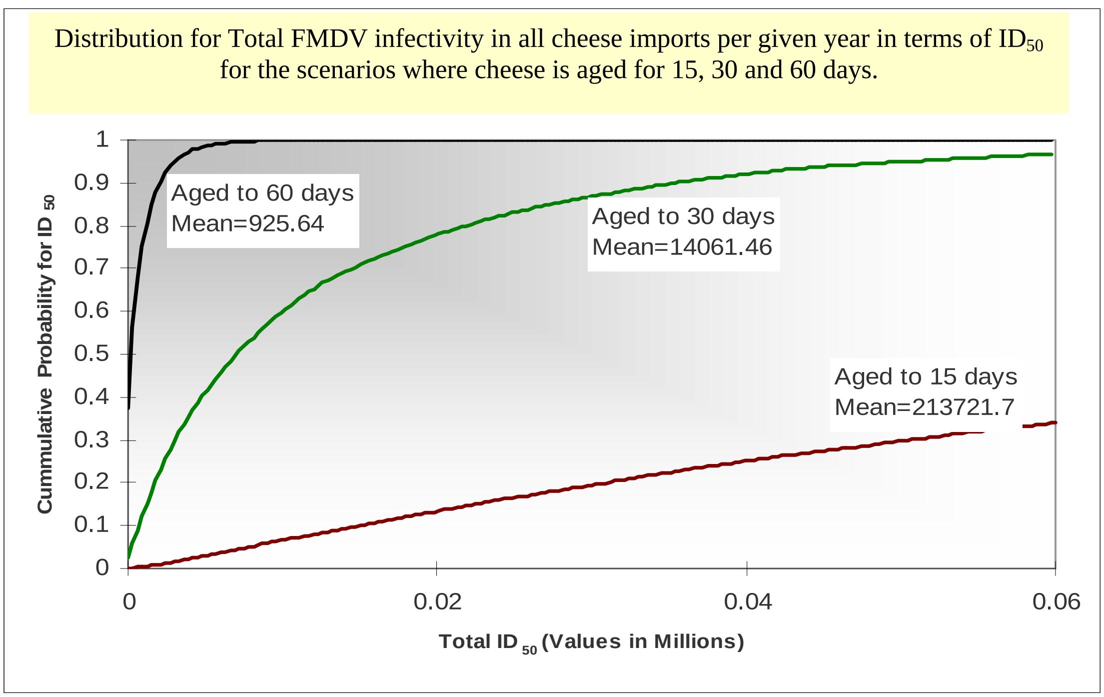
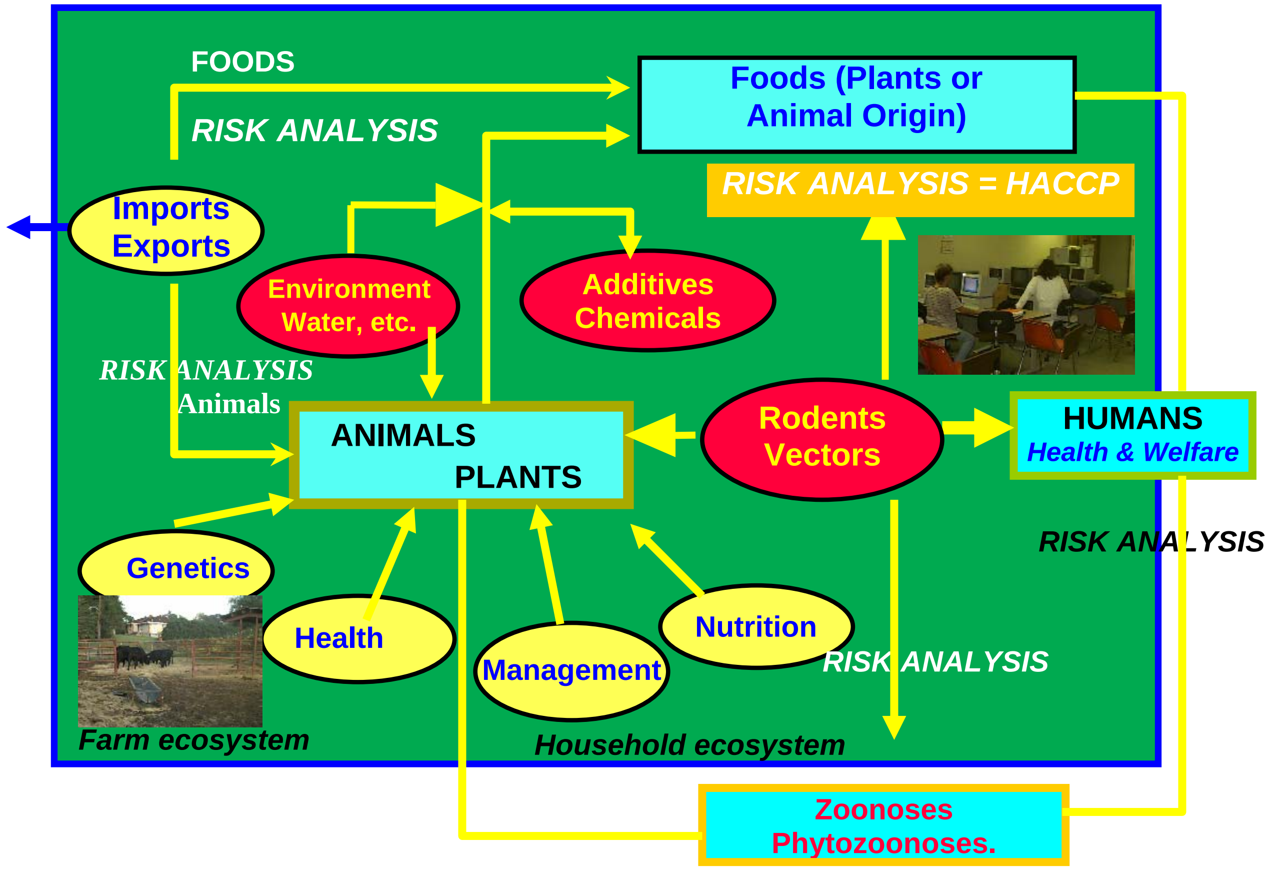


Table 2. Summary of Risk Analysis Workshops in Sub-Saharan Africa (2002 – 2003) by disciplines representation

REGION	Country	No. of participants				
		Veterinary Medicine	Plant Science/Health	Food Safety	Others	Total
Eastern Africa (Addis Ababa, Ethiopia)	Kenya	2	2	0	1	5
	Ethiopia	6	4	0	0	10
	Uganda	4	0	0	0	4
	Tanzania	5	0	0	0	5
Subtotal	**(Four countries)**	**17**	**6**	**0**	**1**	**24**
Western Africa (Accra, Ghana)	Ghana	0	7	0	1	8
	Nigeria	2	0	2	0	4
	Senegal	0	3	0	0	3
	Mali	1	0	0	0	1
	Ivory Coast	0	2	0	0	2
Subtotal	**(Five countries)**	**3**	**12**	**2**	**1**	**18**
Southern Africa (Pretoria, South Africa)	Namibia	1	0	0	1	2
	Zambia	0	1	0	1	2
	Malawi	0	2	0	0	2
	Botswana	1	2	2	2	7
	Swaziland	1	0	0	0	1
	South Africa	3	6	0	2	11
Subtotal	**(Six countries)**	**6**	**11**	**2**	**6**	**25**
Grand total	**15 countries**	**26**	**29**	**4**	**8**	**67**

Figure 5. ***Linking HACCP and Risk*** *Analysis*: The **Framework…HACCP and Risk Analysis Linkage**



The Role of Risk Assessment in Managing Risk

TUSKEGEE UNIVERSITY

Agricultural Outlook Forum 2005

Arlington, Virginia
Feb. 24-25, 2005

College of Veterinary Medicine, Nursing & Allied Health

Tsegaye Habtemariam DVM, MPVM, PhD
Professor of Epidemiology & Biomedical Informatics
Associate Dean for Research & Graduate Studies

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The Center for Computational Epidemiology, Bioinformatics and Risk Analysis (CCEBRA) *http://compepid.tuskegee.edu*

Multidisciplinary Team… ………..and Partnerships

TUSKEGEE UNIVERSITY

Center for Computational Epidemiology, Bioinformatics & Risk Analysis (CCEBRA)

The Team

- *B. Tameru -Mathematics*
- *Saul T. Wilson, Epid/Pub. Hlth*
- *D. Nganwa - Epid/Pub. Hlth*
- *O. Ayanwale - Epid/Pub. Hlth*
- *V. Robnett - Scientific Visualiz.*
- *A. Ahmad - Statistics*
- *A. Afroze - Computational Sc.*
- *A. Steele - Databases*
- *T. Habtemariam - Epidemiology*

Collaborators

- USDA/APHIS
- USDA/FSIS, USDA/ORACBA
- USDA/CSREES
- The Harvard Center for Risk Analysis
- NIH, NSF and Others
- University of Maryland - Engineering

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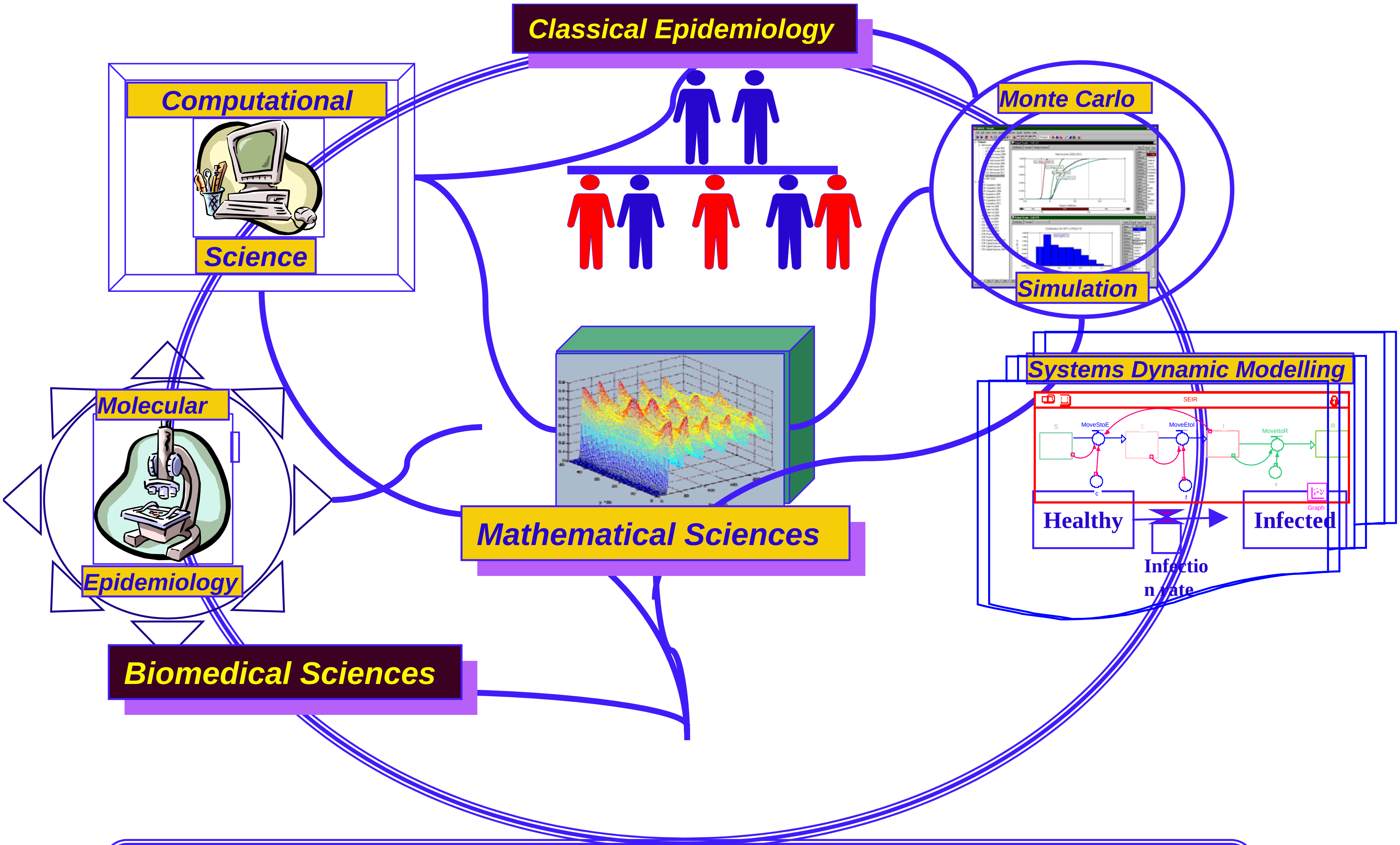

Computational Epidemiology

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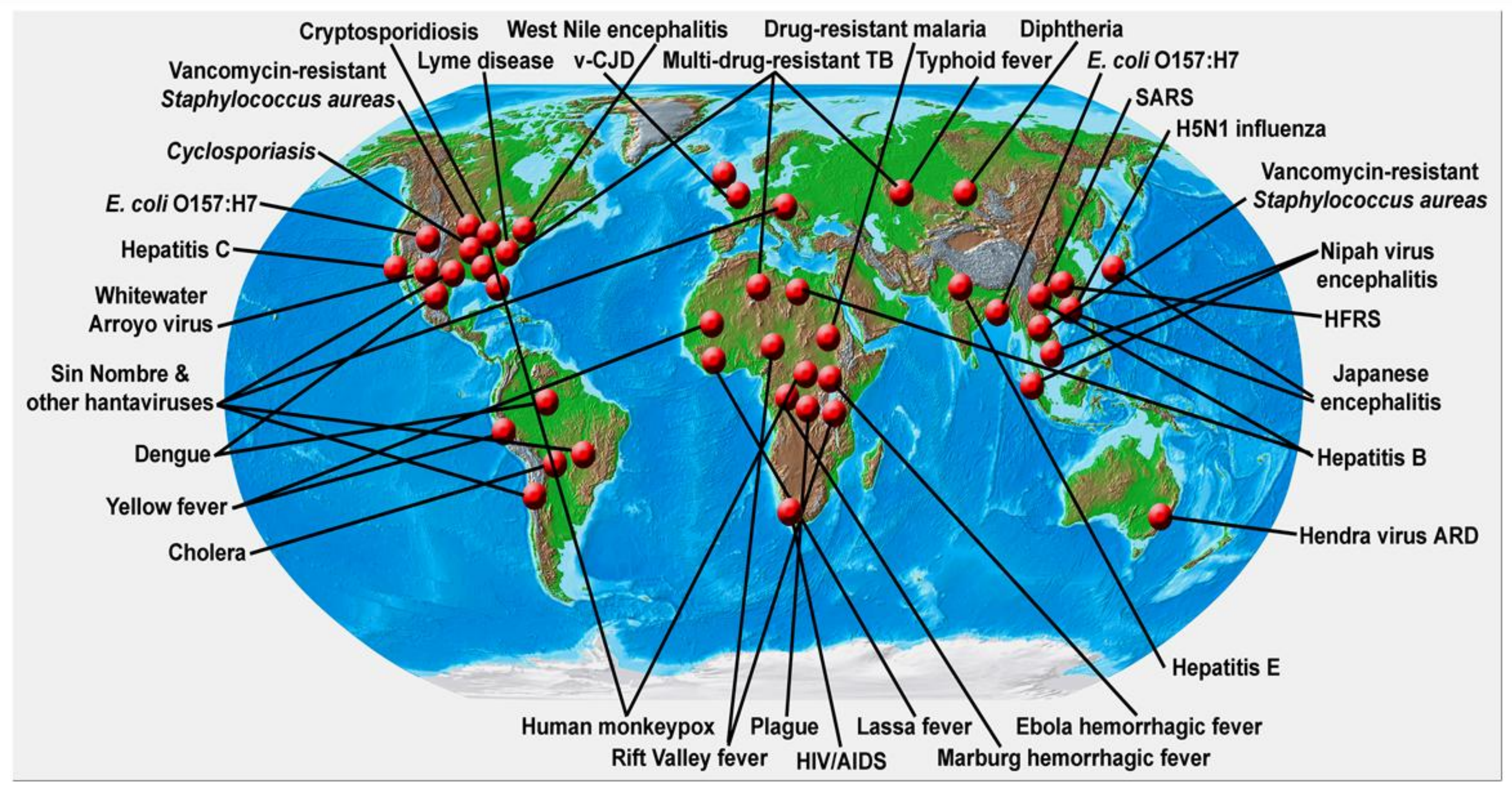
Risk Challenges of the New Century

New, Emerging & Re-emerging Diseases, 2004



"Eleven out of the last 12 human emerging infectious diseases in the world have arisen from animal sources. So what we really need to work on is the relationship between the human health surveillance system and the animal health surveillance system. One very important point of intersection is the laboratories. We have to do more to share our laboratory capacity...."

Dr. Julie Gerberding
Director, CDC
News Conference
Jan 2004

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Global Trade - The WTO & SPS???

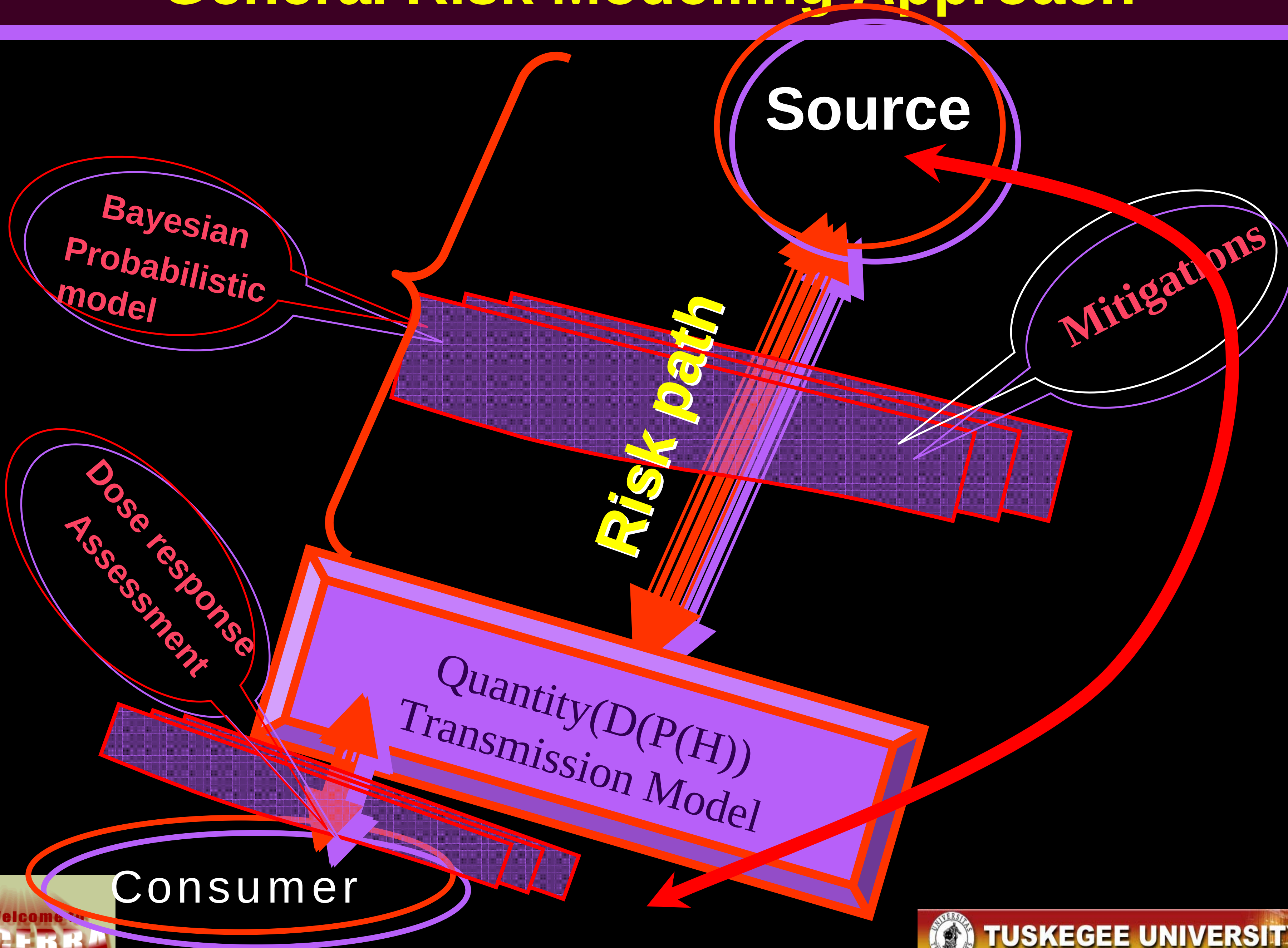
SPS Article 5.1

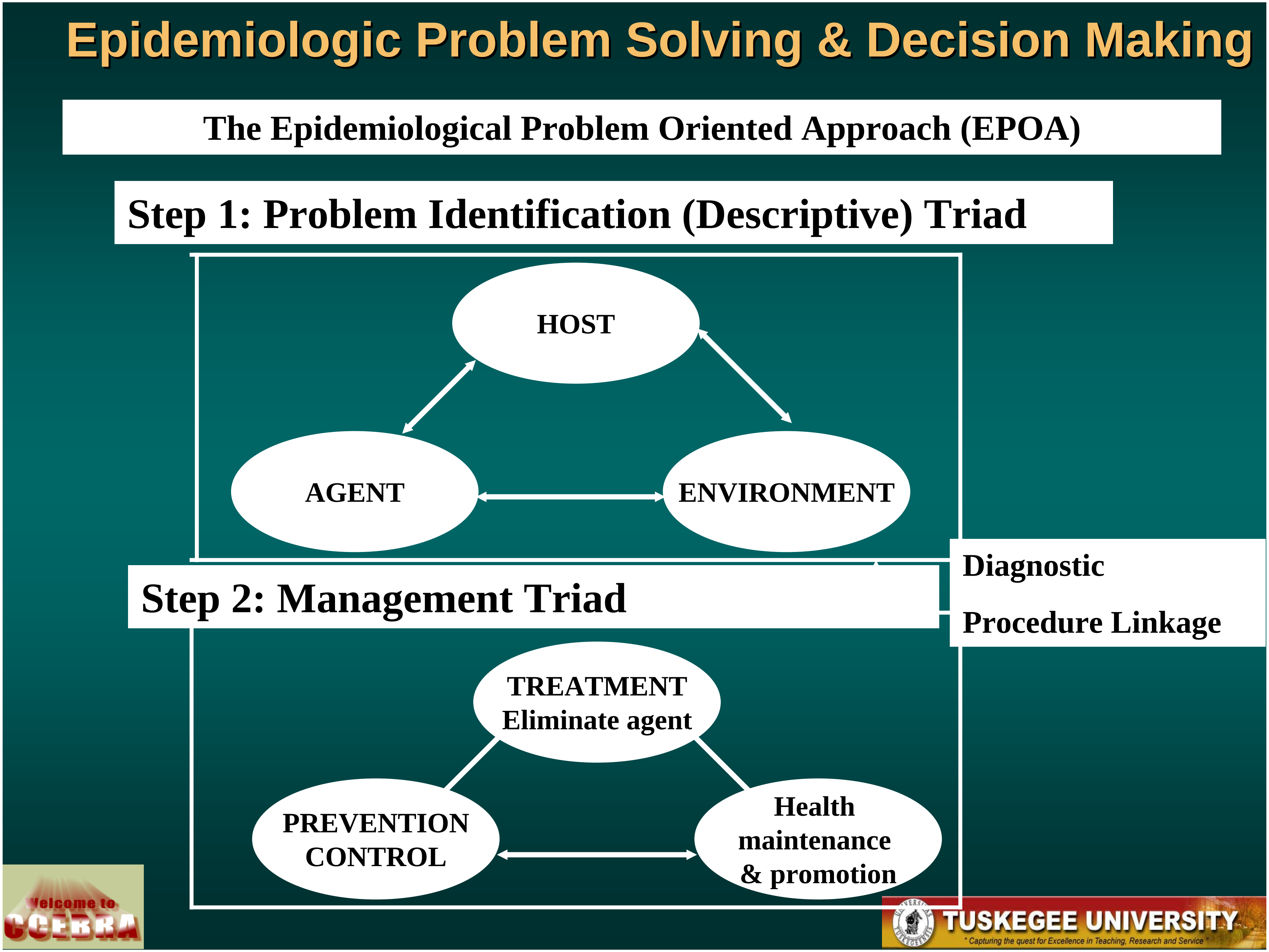
"Members shall ensure that their SPS measures are based on an assessment… of the risks to human, animal or plant life or health.."

Article 9.1
Technical Assistance

- Members agree to facilitate the provision of technical assistance to other Members, especially developing country Members, either bilaterally or through the appropriate international organizations.

General Risk Modelling Approach




Epidemiologic Problem Solving & Decision Making
The Epidemiological Problem Oriented Approach (EPOA)
Step 1: Problem Identification (Descriptive) Triad
HOST
AGENT
ENVIRONMENT
Diagnostic
Procedure Linkage
Step 2: Management Triad
TREATMENT
Eliminate agent
PREVENTION
CONTROL
Health
maintenance
& promotion
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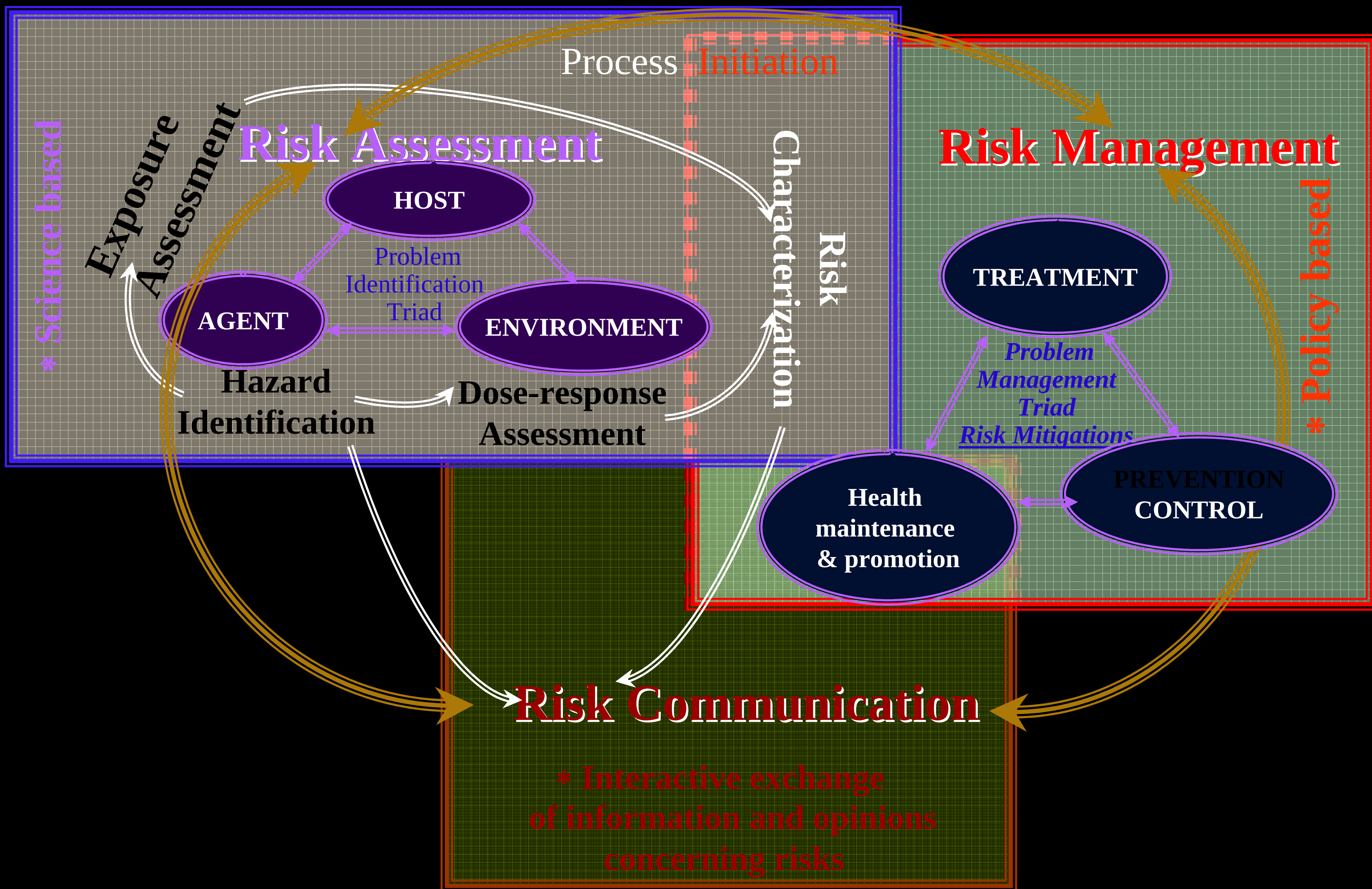
Risk Analysis



Key Issues - Risk Analysis & Modelling

Conceptual Framework

- The Systems Approach…
- Epidemiologic Framework….
- Integrate Time and Space (Use of GIS)

Key Issues

Scientific Evidence: Surveillance & Data Gathering

Risk Modelling Coupled with Epidemiologic Methods

Decomposing Risk Agent Transmission Pathways

Accounting for Mitigations

Case Examples

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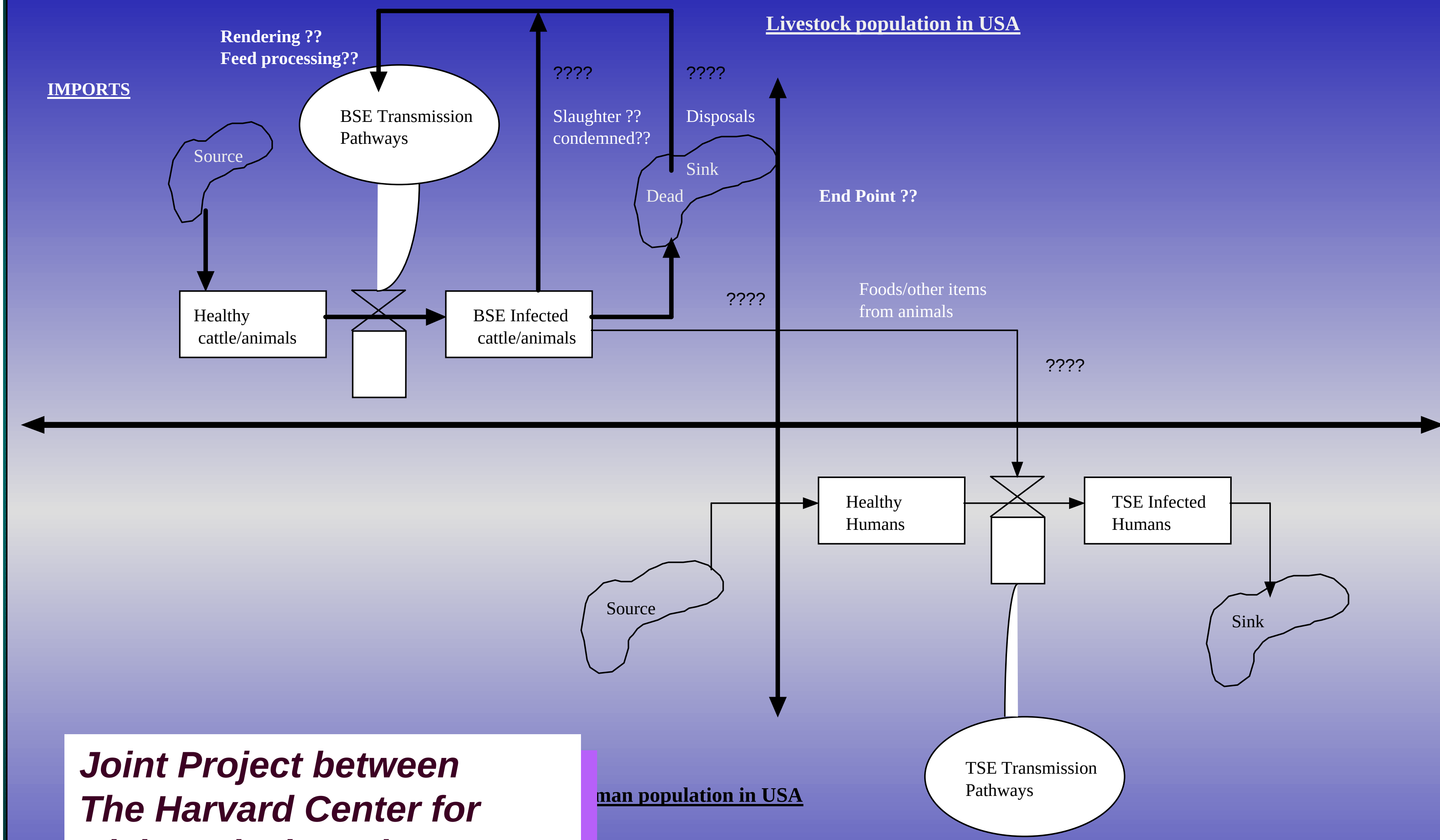
__Conceptual Epidemiologic Framework for Animal/Human Link in BSE__

__Link to Model__



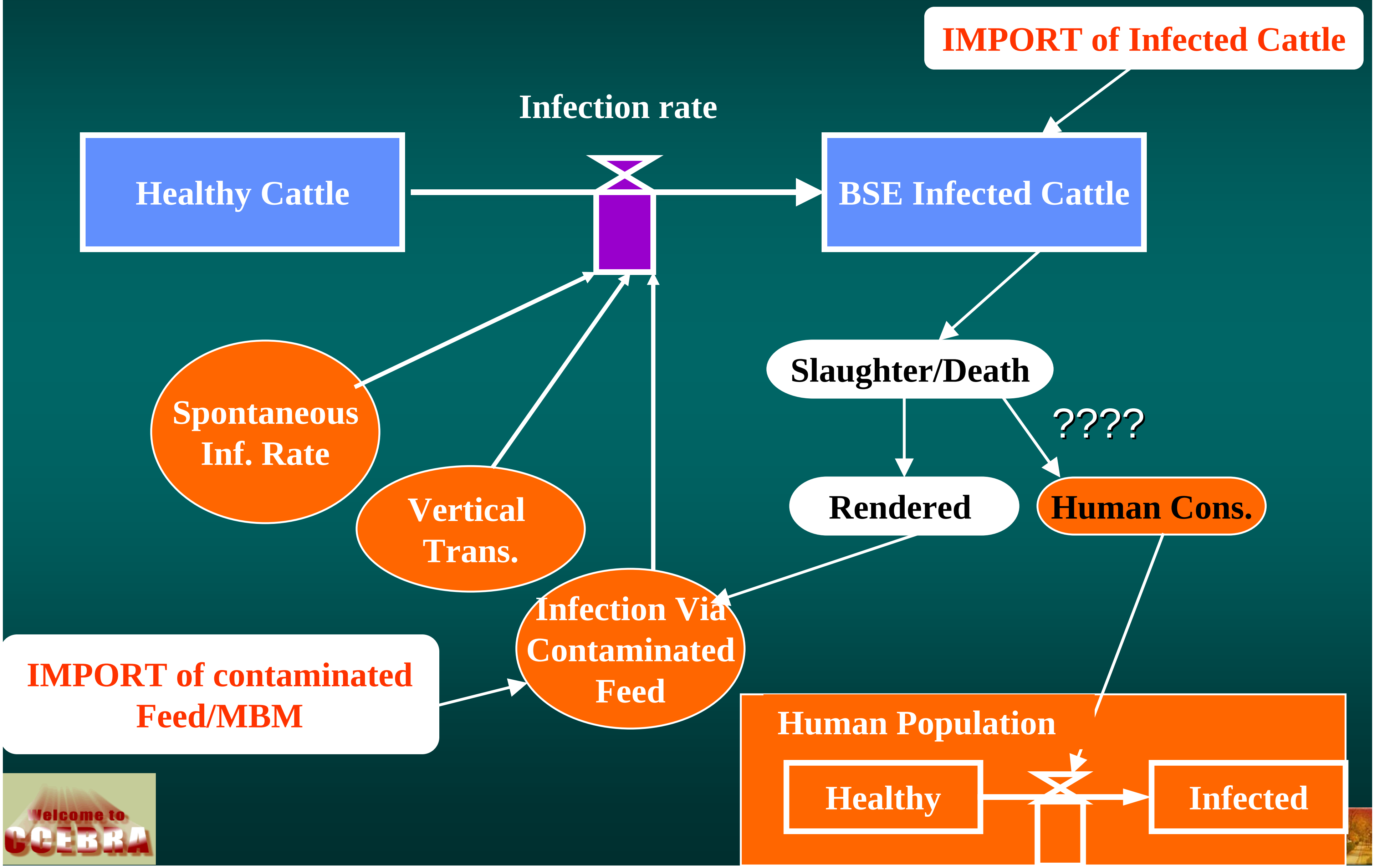
Joint Project between The Harvard Center for Risk analysis and CCEBRA Of CVMNAH

Habtemariam, T., Tameru, B., Nganwa, D., Ayanwale, L., Ahmed, A., Poryang, D., Abdelrahman, H. Gray, G., Cohen, J., Kreindel, S. 2002, *Application of Systems Analysis in Modelling the Risk of Bovine Spongiform Encephalopathy (BSE)*, Kybernetes, The International Jouurnal of Suystems & Cybernetics, Vol. 31, No. 9/10, 1380 – 1390.

Cohen, J., Duggar, K., Gray, G.M., Kriendel, S., Abdelrahman, H., Habtemariam, T., Oryang, D., and Tameru, B. 2001, Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States, http://www.aphis.usda.gov/lpa/issues/issues.html.

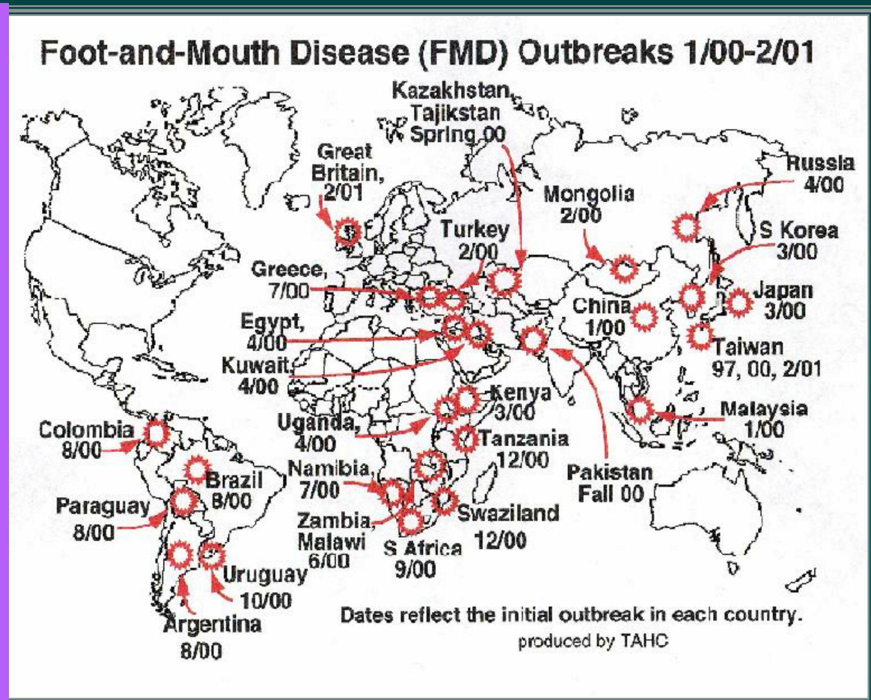
Cohen, J., Duggar, K., Gray, G.M., Kriendel, S., Gubara, H., Habtemariam, T., Oryang, D., and Tameru, B. 2004, A Simulation Model for Evaluating the Potential for Spread of Bovine Spongiform Encephalopathy , In: Prions and Mad Cow Disease, edited by brian K. Nunnaly and Ira S. Krull, Marcel Dekker, inc. NY, NY, pp. 61 – 123, 2004.

<u>Pathway Analysis:</u> How can US Cattle be infected via import of Cattle/Feed from Country X?



Is the USA at Risk to FMD & Others??

The FMD Epidemic



The FMD Outbreak in Great Britain

- Probably up to 10 million cattle were slaughtered during the first 5 months.
- Cost of outbreak estimated to be about 20 billion pounds.
- Severe impact on livestock industry and related areas.

- **US has ten times the livestock population of UK.**

Case Example

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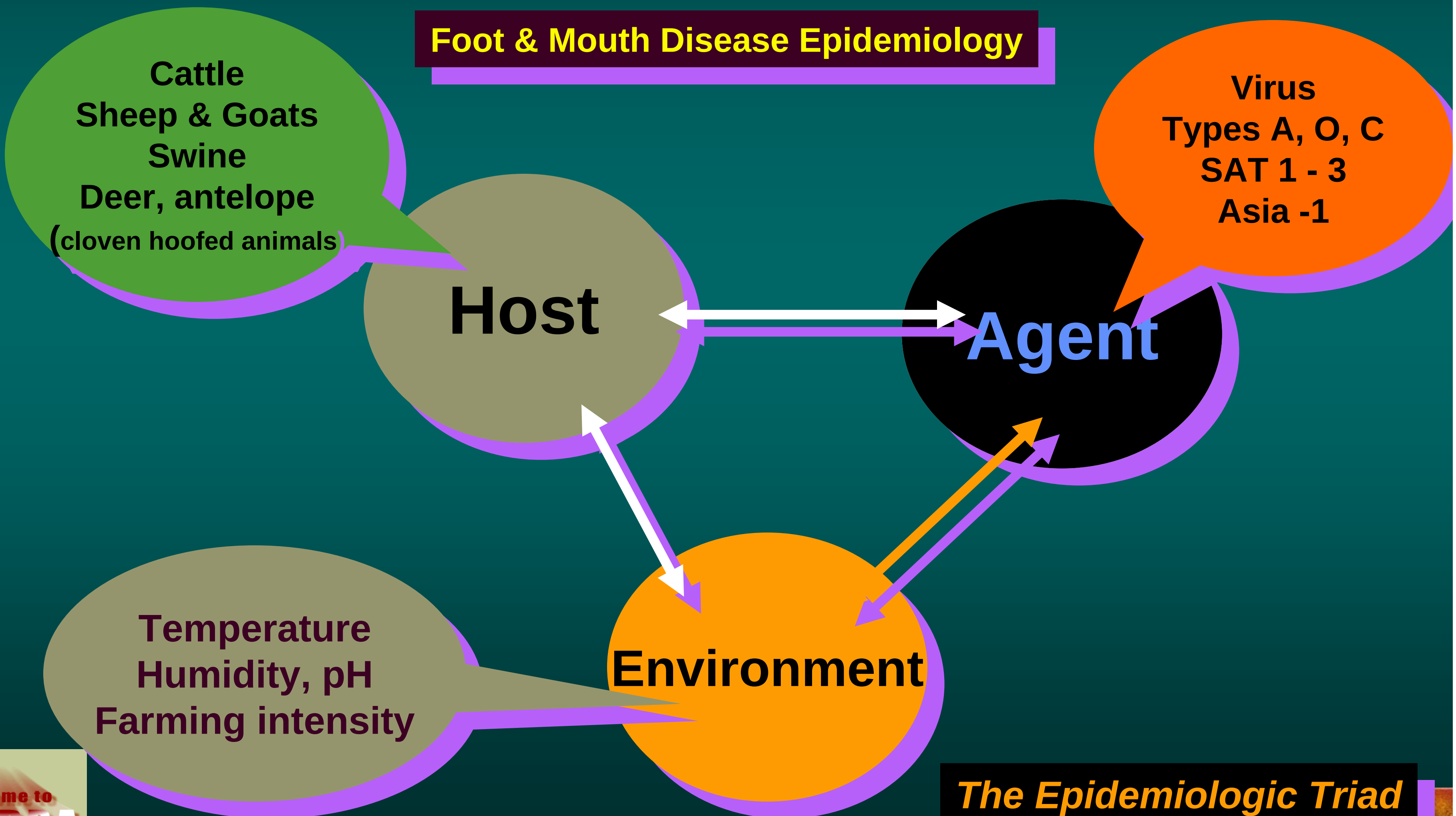
The Epidemiologic Framework …for Risk Assessment

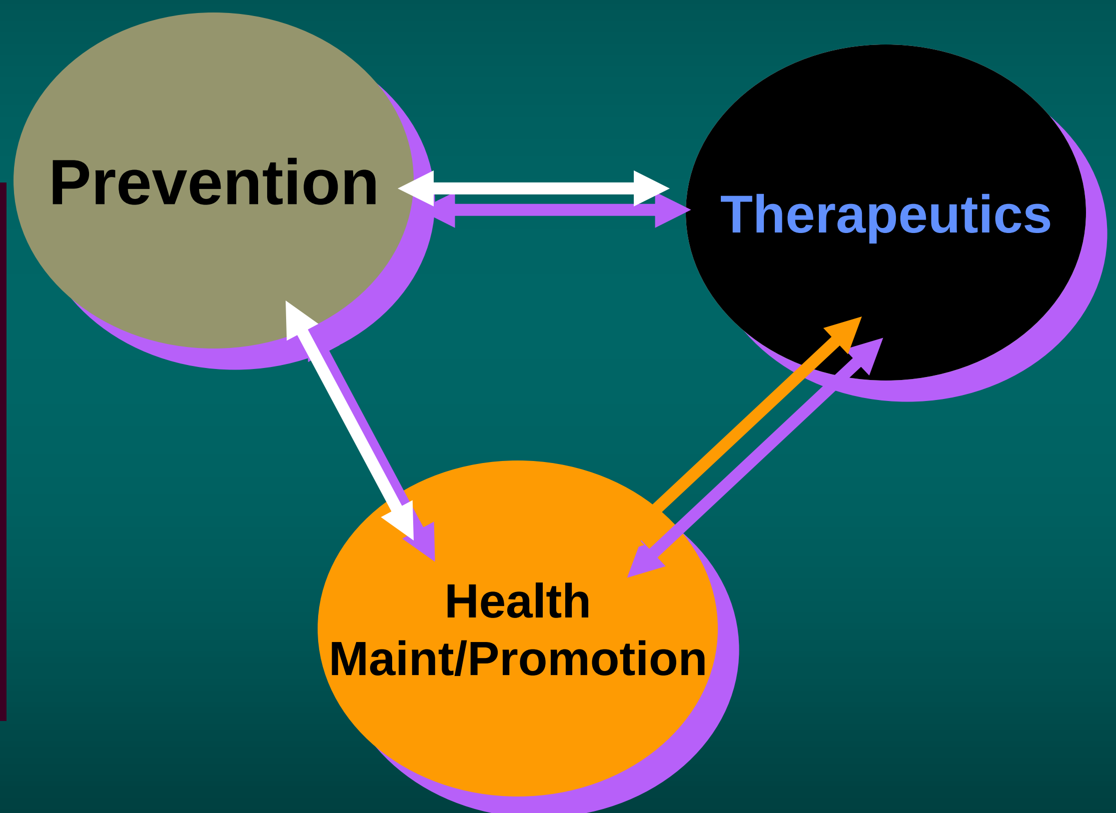


The Epidemiologic Triad

Problem Management Triad
Risk Mitigations

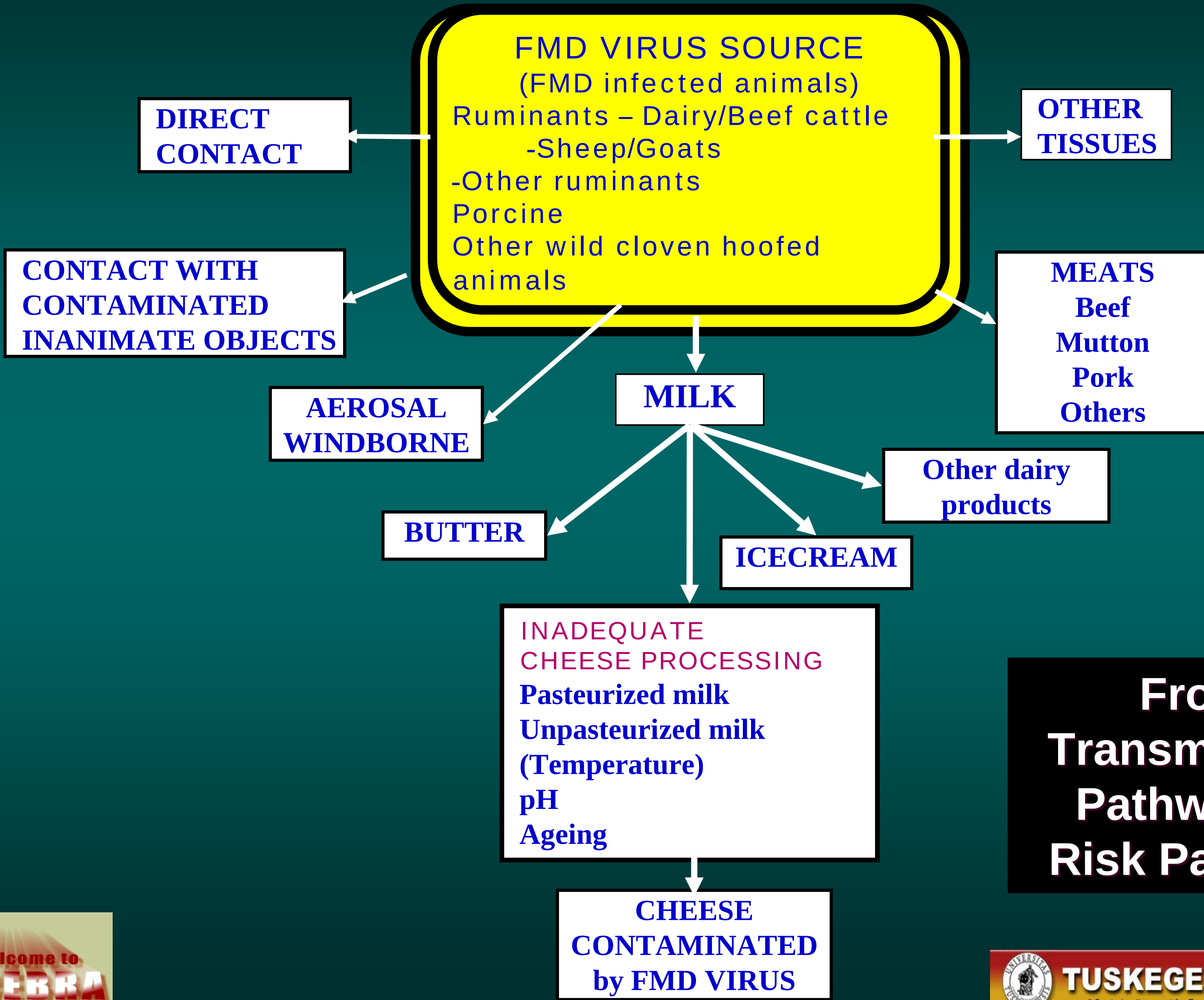
MITIGATIONS
- *Veterinary services*
- *Vaccinations*
- *Surveillance systems*
- *Test systems*

At processing:
- *Ante/post mortem exams*
- *Removal of nodes, bones*
- *Maturation (pH of 5.8)*



Incorporate Risk Mitigations in Model

Transmission Pathway of Foot and Mouth Disease Virus (Emphasis in milk used for cheese production)



From Transmission Pathway to Risk Pathway

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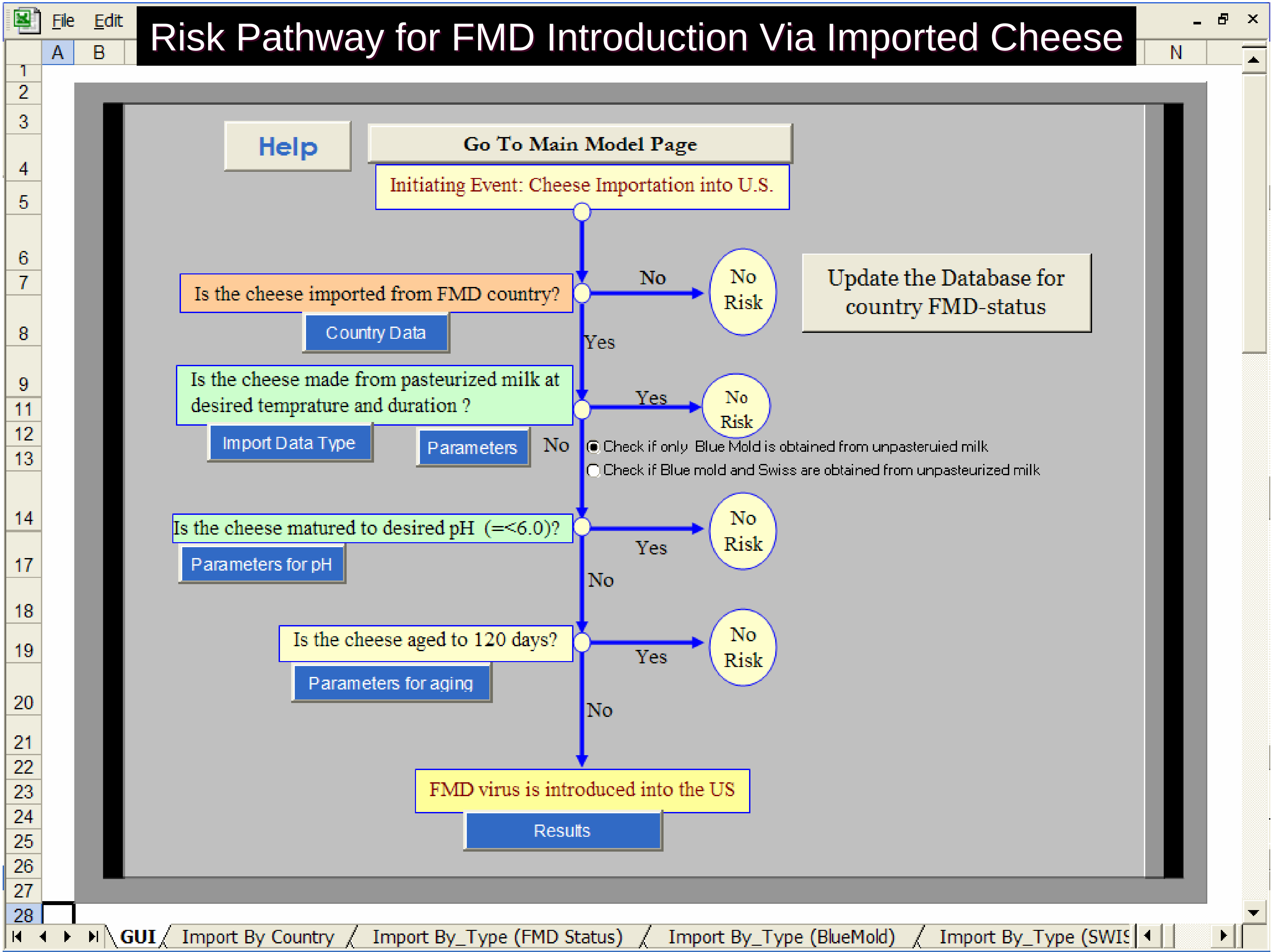
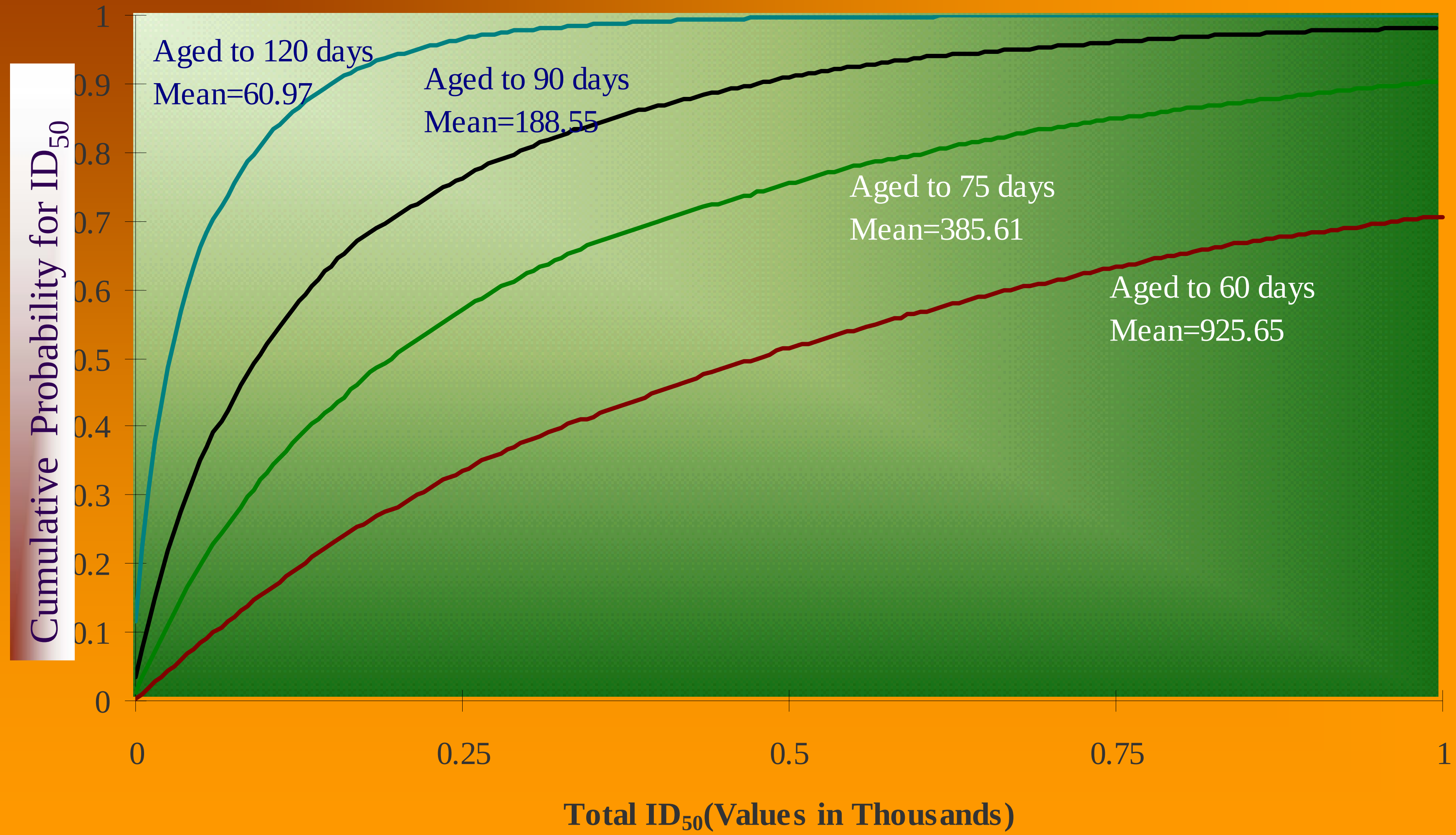


Risk Pathway for FMD Introduction Via Imported Cheese
Help
Go To Main Model Page
Initiating Event: Cheese Importation into U.S.
Is the cheese imported from FMD country?
Country Data
No
No Risk
Update the Database for country FMD-status
Yes
Is the cheese made from pasteurized milk at desired temprature and duration ?
Import Data Type
Parameters
Yes
No Risk
No
Check if only Blue Mold is obtained from unpasteruied milk
Check if Blue mold and Swiss are obtained from unpasteurized milk
Is the cheese matured to desired pH (=<6.0)?
Parameters for pH
Yes
No Risk
No
Is the cheese aged to 120 days?
Parameters for aging
Yes
No Risk
No
FMD virus is introduced into the US
Results
GUI
Import By Country
Import By_Type (FMD Status)
Import By_Type (BlueMold)

Cumulative distribution of FMD total virus infectivity in terms of ID50 in all imported cheese: scenarios where cheese is aged for 60, 75, 90, and 120 days



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QRA Risk of Citrus Importation

Citrus Canker

Citrus Black Spot

Sweet Orange Scab

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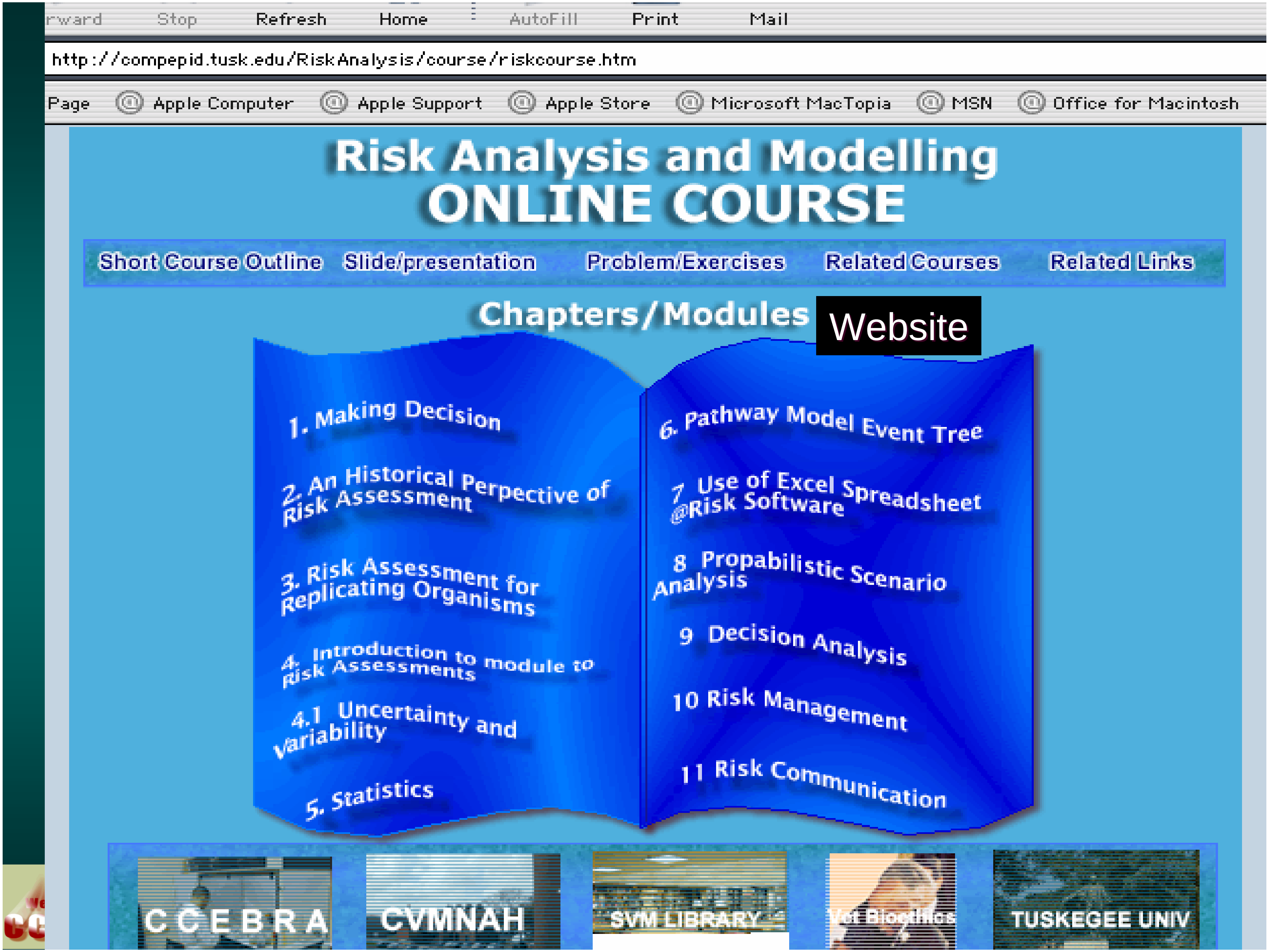
Website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http://compepid.tusk.edu/RiskAnalysis/course/riskcourse.htm
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Apple Computer
Apple Support
Apple Store
Microsoft MacTopia
MSN
Office for Macintosh
Risk Analysis and Modelling
ONLINE COURSE
Short Course Outline
Slide/presentation
Problem/Exercises
Related Courses
Related Links
Chapters/Modules
1. Making Decision
2. An Historical Perpective of Risk Assessment
3. Risk Assessment for Replicating Organisms
4. Introduction to module to Risk Assessments
4.1 Uncertainty and Variability
5. Statistics
6. Pathway Model Event Tree
7 Use of Excel Spreadsheet @Risk Software
8 Propabilistic Scenario Analysis
9 Decision Analysis
10 Risk Management
11 Risk Communication
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CVMNAH
SVM LIBRARY
Vet Bioethics
TUSKEGEE UNIV

Workshop in
Addis Ababa, Ethiopia

Workshop in Accra, Ghana

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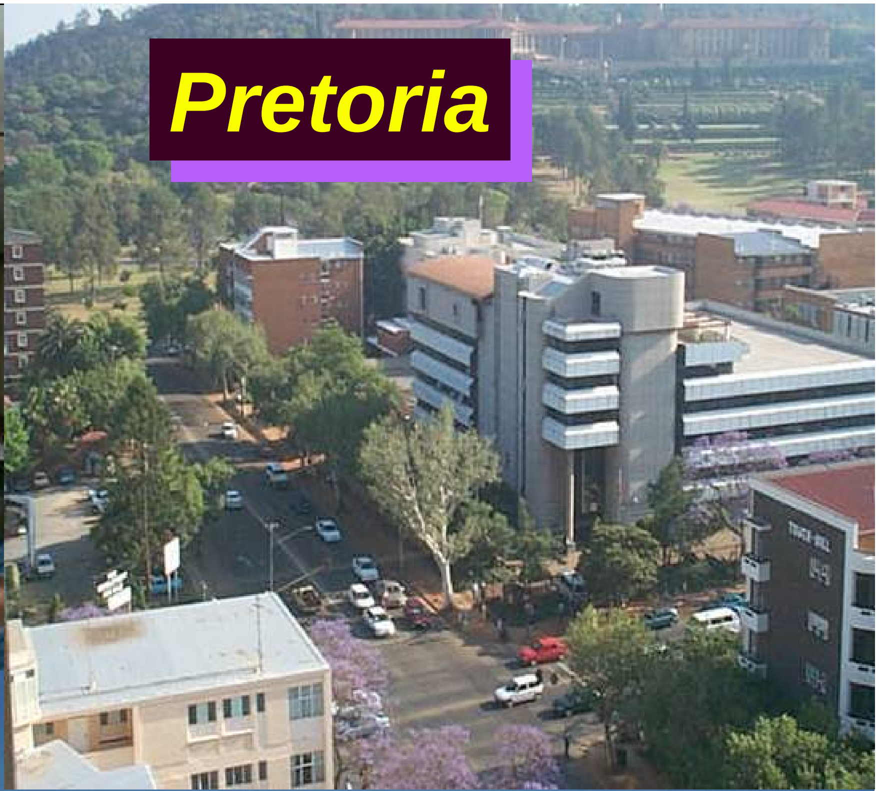

Pretoria

Soweto

Workshop in
Pretoria, South Africa

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Participants - Risk Analysis Workshops

REGION	Country	No. of participants				
		Veterinary Medicine	Plant Science/Health	Food Safety	Others	Total
Eastern Africa (Addis Ababa, Ethiopia)	Kenya	2	2	0	1	5
	Ethiopia	6	4	0	0	10
	Uganda	4	0	0	0	4
	Tanzania	5	0	0	0	5
Sub total	**(Four countries)**	**17**	**6**	**0**	**1**	**24**
Western Africa (Accra, Ghana)	Ghana	0	7	0	1	8
	Nigeria	2	0	2	0	4
	Senegal	0	3	0	0	3
	Mali	1	0	0	0	1
	Ivory Coast	0	2	0	0	2
Sub total	**(Five countries)**	**3**	**12**	**2**	**1**	**18**
Southern Africa (Pretoria, South Africa)	Namibia	1	0	0	1	2
	Zambia	0	1	0	1	2
	Malawi	0	2	0	0	2
	Botswana	1	2	2	2	7
	Swaziland	1	0	0	0	1
	South Africa	3	6	0	2	11
Sub total	**(Six countries)**	**6**	**11**	**2**	**6**	**25**
Grand total	**15 countries**	**26**	**29**	**4**	**8**	**67**

International Training: The Benefits

Building International Coalitions

***Reducing Domestic threats* Through International Risk Reduction Activities (*Training/Tech Transfer*)**

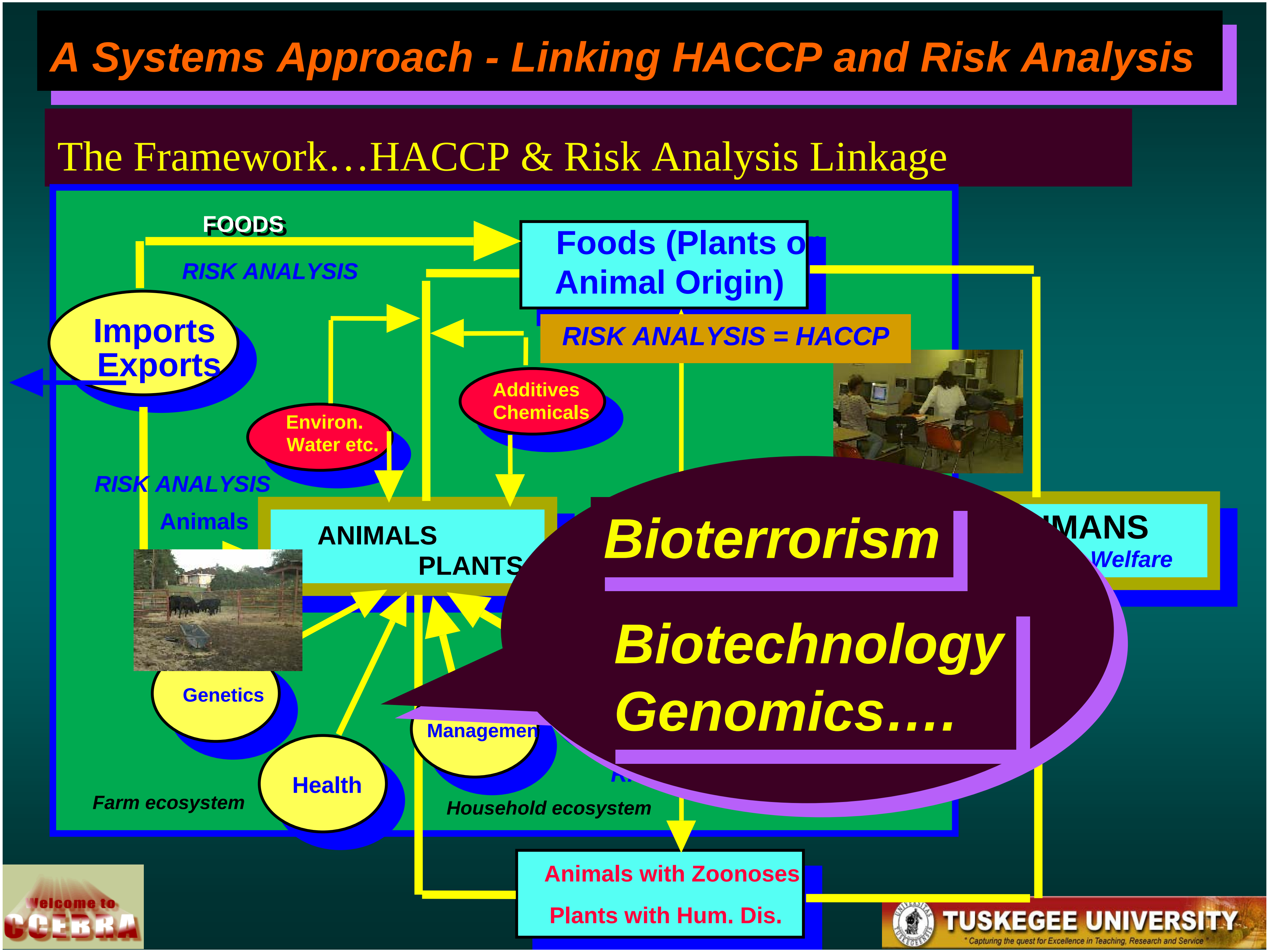
Assist in identifying and preventing the spread of risk agents at the source

Reducing the risk of invasive species by enhancing risk analysis capabilities

Promote Global Trade

Expanding & Advancing Risk Assessment Tools

Sponsored by USDA & Tuskegee University


A Systems Approach - Linking HACCP and Risk Analysis
The Framework…HACCP & Risk Analysis Linkage
FOODS
RISK ANALYSIS
Foods (Plants o
Animal Origin)
RISK ANALYSIS = HACCP
Imports
Exports
Additives
Chemicals
Environ.
Water etc.
RISK ANALYSIS
Animals
ANIMALS
PLANTS
Welfare
Bioterrorism
Biotechnology
Genomics….
Genetics
Managemen
Health
Farm ecosystem
Household ecosystem
Animals with Zoonoses
Plants with Hum. Dis.
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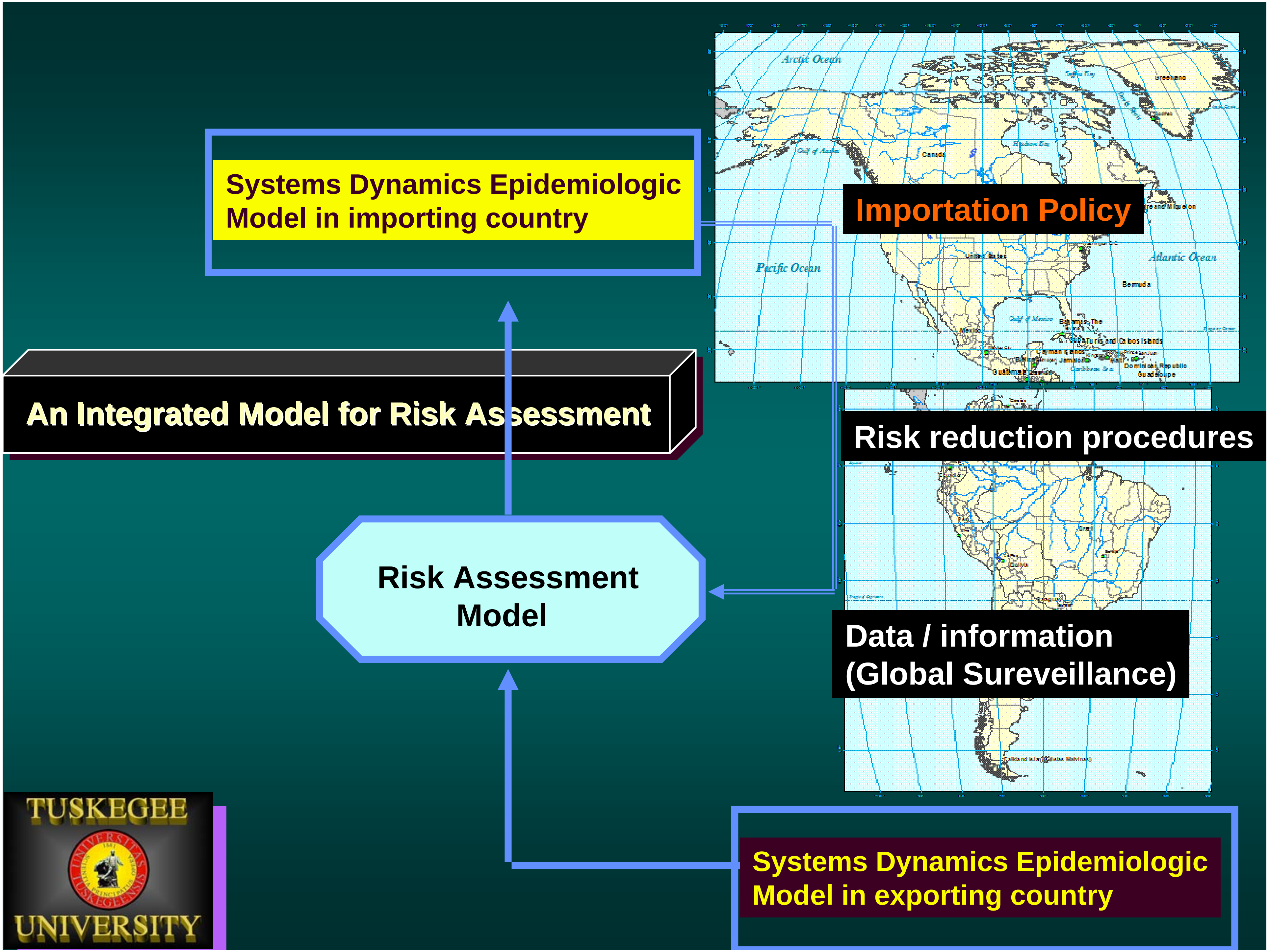
An Integrated Model for Risk Assessment
Systems Dynamics Epidemiologic Model in importing country
Importation Policy
Risk reduction procedures
Risk Assessment Model
Data / information (Global Sureveillance)
Systems Dynamics Epidemiologic Model in exporting country
Arctic Ocean
Pacific Ocean
Atlantic Ocean
Greenland
Bermuda
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Summary: Strategic Challenges & Opportunities

- **Fast Transportation Systems**
- **Interconnectedness**
- **Global Trade (The WTO and SPS Regulations)**
- **Demographic & Ethnic Diversity**

- ***Unintentional Introductions of Agents***
- ***Intentional Introductions - Bioterrorism/Agroterrorism***

1. Surveillance! Epidemiologic Intelligence Gathering Supported by Reliable Diagnostic Laboratories!

2. Global Digital Resources for Reporting & Sharing Information Fast Response Teams & Strategies

3. Long Term Commitment to International Training & Technology Transfer

4. Continuous Learning & Expanding/Optimizing Strategic Tools

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A Guiding Philosophy……

"Knowledge cannot start from nothing….
Nor yet from observation. The advance of knowledge consists mainly in the modification of earlier knowledge".

"Karl Popper

In

The Logic of Scientific Discovery"

And FINALLY...

Thank You...
See You in Cyberspace

Habtemart@tuskegee.edu
Http://compepid.tuskegee.edu